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Guidance for the Reregistration of Pesticide Products Containing 2,4-Dichlorophenoxyacetic Acid (2,4-D) as the Active Ingredient

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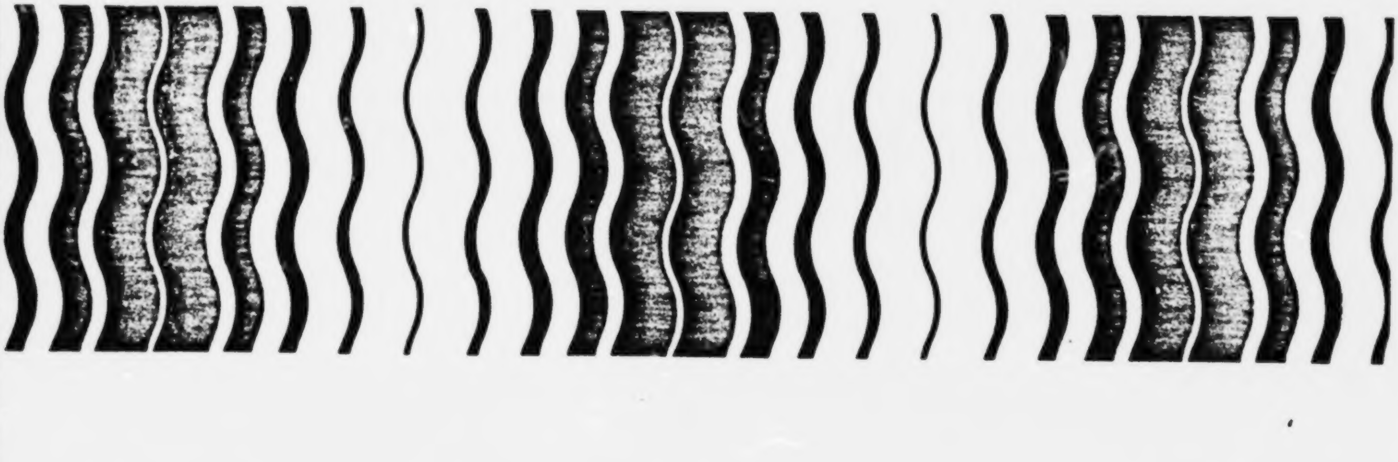
Guidance for the Reregistration of Pesticide Products Containing 2,4-DICHLORO-PHENOXYACETIC ACID (2,4-D) as the Active Ingredient



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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
2,4-DICHLOROPHENOXYACETIC ACID
(2,4-D)
AND ITS SALTS, AMINES AND ESTERS
AS THE ACTIVE INGREDIENT

CAS REGISTRY NO. 94-75-7

OPP CHEMICAL CODE 030001 (ACID)

EPA CASE NUMBER -- GS-0073

SEPTEMBER 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI: Acceptable Daily Intake - an acceptable daily intake of pesticide residue based on a complete data base.

a.i.: Active ingredient

CAS: Chemical Abstract Services (number)

Core Classification: A general guide to the acceptability of data for the purpose of supporting registration:

Guideline - studies which satisfy Agency data requirements;

Minimum - studies which are acceptable to support registration of pesticide products but were not necessarily done according to Agency guidelines;

Supplementary - studies which are scientifically sound, thus information may be useful; however, the studies were performed under conditions that deviated substantially from recommended protocols. Studies do not meet guidelines requirements and thus do not support registration of a product; and,

Invalid - studies which are deficient in some vital parameter or which have been judged not to be scientifically sound or whose reliability is seriously questioned.

CSF: Confidential Statement of Formula

EEC: Estimated Environmental Concentration - estimated pesticide concentration in the environment (terrestrial or aquatic ecosystem).

EPA: The U.S. Environmental Protection Agency (Agency)

FIFRA: Federal Insecticide, Fungicide and Rodenticide Act

LC$_{50}$: Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50 percent of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/l or ppm).

LD$_{50}$: Median lethal dose - a statistically derived single dose that can be expected to cause death in 50 percent of test animals when administered by the

	route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).
LOEL:	Lowest Observed Effect Level
MPI:	Maximum Permissible Intake
MRID:	Master Record Identification (number) - EPA's system of tracking studies used in support of registration.
MP:	Manufacturing-use product
NPDES:	National Pollution Discharge Elimination System
NOEL:	No Observed Effect Level - the maximum dose used in a test which produces no observed adverse effects.
OPP:	The Office of Pesticide Programs of the U.S. EPA
OES:	The Office of Endangered Species, U.S. Fish and Wildlife Service
PHI:	Preharvest Interval
PPM:	Parts per million
RfD:	Reference Dose
Technical:	Active ingredient as manufactured
TMRC:	Theoretical Maximum Residue Contribution - an estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure then adding the exposure figures for each crop. TMRC is usually expressed in terms of mg ai/day, assuming a 60 kg person.

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews and Compendium of Uses may be obtained from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161. Tel: (703) 487-4650.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C. in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICALS COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICALS

This Standard covers 2,4-dichlorophenoxyacetic acid (2,4-D), and its inorganic salts, amines and esters.

Most often, the acid is not formulated as an end-use product; instead the typical end-use product, as applied, is usually a formulation of an amine or ester of the parent compound. With these formulations, the esters or amines may greatly influence the physical characteristics, biological activity and environmental fate of the chemical. The Agency has little or no data to evaluate the behavior of these compounds in the environment. Therefore, the data requirements in this Standard address not only the acid and its inorganic salts but also the amine salts and esters.

Identifying characteristics, codes and structures are shown below:

Chemical Name: 2,4-D acid
Empirical Formula: $C_8H_6Cl_2O_3$
Molecular Weight: 221.0
CAS Registry Number: 94-75-7
OPP Chemical Code: 030001

Chemical Name: Lithium salt
Empirical Formula: $C_8H_5Cl_2LiO_3$
Molecular Weight: 227 (estimate)
CAS Registry Number: 3766-27-6
OPP Chemical Code: 030002

Chemical Name: Sodium salt
Empirical Formula: $C_8H_5Cl_2NaO_3$
Molecular Weight: 243.03 (anhydrous)
CAS Registry Number: 2702-72-9
OPP Chemical Code: 030004

Chemical Name: Ammonium salt
Empirical Formula: $C_8H_9Cl_2NO_3$
Molecular Weight: 238.07
CAS Registry Number: 2707-55-3
OPP Chemical Code: 030005

Chemical Name: Alkanolamine salt (of the ethanol and isopropanol series - a mixture of compounds described under OPP chemical code numbers 030021 and 030024)
Empirical Formula: Combination
Molecular Weight: Combination
CAS Registry Number: NA
OPP Chemical Code: 030010

Chemical Name: Alkylamine (C_{12}) salt (formulated only as an end-use product in combination with 2,4-D, alkylamine (Cl_4) salt)
Empirical Formula: $C_{20}H_{33}Cl_2NO_3$
Molecular Weight: 406 (estimate)
CAS Registry Number: 2212-54-6
OPP Chemical Code: 030011

Chemical Name: Alkylamine (C_{14} salt (formulated only as an end-use product in combination with C_{12} salt)
Empirical Formula: $C_{22}H_{37}Cl_2NO_3$
Molecular Weight: 434 (estimate)
CAS Registry Number: 25685-18-9
OPP Chemical Code: 030013

Chemical Name: Alkylamine (derived from tall oil) salt (tall oil is a by-product of the wood pulp industry containing a mixture of rosin acids, oleic acid, linoleic acid, and other compounds)
Empirical Formula: Complex mixture
Molecular Weight: Complex mixture
CAS Registry Number: NA
OPP Chemical Code: 030014

Chemical Name: Diethanolamine Salt
Empirical Formula: $C_{12}H_{17}Cl_2NO_5$
Molecular Weight: 326.18
CAS Registry Number: 5742-19-8
OPP Chemical Code: 030016

Chemical Name: Diethylamine salt
Empirical Formula: $C_{12}H_{17}Cl_2NO_3$
Molecular Weight: 294.18
CAS Registry Number: 20940-37-8
OPP Chemical Code: 030017

Chemical Name: Dimethylamine salt
Empirical Formula: $C_{10}H_{13}Cl_2NO_3$
Molecular Weight: 266.13
CAS Registry Number: 2008-39-1
OPP Chemical Code: 030019

Chemical Name: N,N-dimethyloleylamine salt (formulated only as an end-use product in combination with 2,4-D acid)
Empirical Formula: $C_{28}H_{47}Cl_2NO_3$
Molecular Weight: 516 (estimate)
CAS Registry Number: 53535-36-7
OPP Chemical Code: 030020

Chemical Name: Ethanolamine salt
Empirical Formula: $C_{10}H_{13}Cl_2NO_4$
Molecular Weight: 282.13
CAS Registry Number: 3599-58-4
OPP Chemical Code: 030021

Chemical Name: Heptylamine salt
Empirical Formula: $C_{15}H_{23}Cl_2NO_3$
Molecular Weight: 336 (estimate)
CAS Registry Number: 37102-63-9
OPP Chemical Code: 030023

Chemical Name: Isopropanolamine salt
Empirical Formula: $C_{11}H_{15}Cl_2NO_4$
Molecular Weight: 296.15
CAS Registry Number: 6365-72-6
OPP Chemical Code: 030024

Chemical Name: Isopropylamine salt
Empirical Formula: $C_{11}H_{15}Cl_2NO_3$
Molecular Weight: 280.04
CAS Registry Number: 5742-17-6
OPP Chemical Code: 030025

Chemical Name: Morpholine salt
Empirical Formula: $C_{12}H_{15}Cl_2NO_4$
Molecular Weight: 308.16
CAS Registry Number: 6365-73-7
OPP Chemical Code: 030028

Chemical Name: N-oleyl-1,3-propylenediamine salt
Empirical Formula: $C_{37}H_{56}Cl_4N_2O_6$
Molecular Weight: 766.6
CAS Registry Number: 2212-59-1
OPP Chemical Code: 030029

Chemical Name: Octylamine salt
Empirical Formula: $C_{16}H_{25}Cl_2NO_3$
Molecular Weight: 350 (estimate)
CAS Registry Number: 2212-53-5
OPP Chemical Code: 030030

Chemical Name: Triethanolamine salt
Empirical Formula: $C_{14}H_{21}Cl_2NO_6$
Molecular Weight: 3770.23
CAS Registry Number: 2569-01-9
OPP Chemical Code: 030033

Chemical Name: Triethylamine salt
Empirical Formula: $C_{14}H_{21}Cl_2NO_3$
Molecular Weight: 322.23
CAS Registry Number: 2646-78-8
OPP Chemical Code: 030034

Chemical Name: Triisopropanolamine salt
Empirical Formula: $C_{17}H_{27}Cl_2NO_6$
Molecular Weight: 412.31
CAS Registry Number: 32341-80-3
OPP Chemical Code: 030035

Chemical Name: N,N-dimethyloleyl-linoleylamine salt
Empirical Formula: Not determined
Molecular Weight: Not determined
CAS Registry Number: 55256-32-1
OPP Chemical Code: 030039

Chemical Name: Butoxyethoxypropyl ester
Empirical Formula: $C_{17}H_{24}Cl_2O_5$
Molecular Weight: 379.28
CAS Registry Number: 1928-57-0
OPP Chemical Code: 030052

Chemical Name: 2-butoxyethyl ester
Empirical Formula: $C_{14}H_{18}Cl_2O_4$
Molecular Weight: 321.20
CAS Registry Number: 1929-73-3
OPP Chemical Code: 030053

Chemical Name: Butoxypropyl ester
Empirical Formula: $C_{15}H_{20}Cl_2O_4$
Molecular Weight: 335.24
CAS Registry Number: 1928-45-6
OPP Chemical Code: 030055

Chemical Name: Butyl ester
Empirical Formula: $C_{12}H_{14}Cl_2O_3$
Molecular Weight: 277.16
CAS Registry Number:94-80-4
OPP Chemical Code: 030056

Chemical Name: Isobutyl ester
Empirical Formula: $C_{12}H_{14}Cl_2O_3$
Molecular Weight: 277.15
CAS Registry Number: 1713-15-1
OPP Chemical Code: 030062

Chemical Name: Isooctyl (2-ethylhexyl) ester
Empirical Formula: $C_{16}H_{22}Cl_2O_3$
Molecular Weight: 333.27
CAS Registry Number: 1928-43-4
OPP Chemical Code: 030063

Chemical Name: Isooctyl (2-ethyl-4-methylpentyl) ester
Empirical Formula: $C_{16}H_{22}Cl2O_3$
Molecular Weight: 333.27
CAS Registry Number: 53404-37-8
OPP Chemical Code: 030064

Chemical Name: Isooctyl (2-octyl) ester
Empirical Formula: $C_{16}H_{22}Cl_2O_3$
Molecular Weight: 333.27
CAS Registry Number: 1917-97-1
OPP Chemical Code: 030065

Chemical Name: Isopropyl ester
Empirical Formula: $C_{11}H_{12}Cl_2O_3$
Molecular Weight: 263.12
CAS Registry Number: 94-11-1
OPP Chemical Code: 030066

Chemical Name: Propylene glycol butyl ether ester
Empirical Formula: $C_{15}H_{20}Cl_2O_4$
Molecular Weight: 335.24
CAS Registry Number: 1320-18-9
OPP Chemical Code: 030072

B. USE PROFILE

Type of Pesticide: Herbicide; Plant Growth Regulator.

Pests Controlled: Broadleaf weeds; grasses and other monocots; woody plants; aquatic weeds; and nonflowering plants.

Registered Uses: Terrestrial, food and nonfood; aquatic, food and nonfood; domestic; and forestry.

Predominant Uses: Postemergent weed control in agricultural crops (approximately 57 percent of total usage; over 45 percent of total usage is on wheat and corn; 20 percent of total usage on pastures and rangelands; other major crops are sorghum, other small grains, rice and sugarcane); the remainder is used on noncrop areas, with a small amount used as a plant growth regulator (in filberts, citrus and potatoes).

Mode of Activity: 2,4-D acid stimulates nucleic acid and protein synthesis affecting the activity of enzymes, respiration and cell division. Broadleaf plants exhibit malformed leaves, stems and roots.

Formulation Types Registered: Granular; amine and ester liquids; and aerosol spray (foam).

Methods of Application: Aerial and ground equipment, knapsack sprayers, pressure and hose-end applicators, and lawn spreaders.

C. BACKGROUND

In 1979 and 1980, the Agency conducted a review of the toxicological studies supporting the registration of 2,4-D and concluded from the studies that continued use of this product would not pose a significant hazard to public health or the environment. However, the Agency determined that additional toxicological data were needed and, in a 1980 Data Call-in (DCI), required the registrants to submit additional studies. Since that time, these studies have been received and reviewed by EPA.

The Agency also reviewed a number of epidemiologic studies, including a new study conducted by the National Cancer Institute (NCI) and the University of Kansas published in 1986, in which the researchers found a correlation between the use by farmers of phenoxy herbicides, including 2,4-D, and an increased cancer risk (non-Hodgkin's lymphoma) among farmers handling such herbicides.

Based on the epidemiologic evidence, in September 1986, the Agency issued a preliminary notification of special review to the registrants of 2,4-D, 2,4-DB and 2,4-DP. The special review process is a mechanism for evaluating and weighing the risks and benefits of a pesticide to determine whether the pesticide and its uses pose unreasonable adverse risks to humans and the environment.

Subsequent to the issuance of the preliminary notification, the epidemiologic evidence underwent further review by the Agency's Office of Pesticide Programs (OPP), by three epidemiologists, two of whom are national experts on epidemiology, and by the FIFRA Scientific Advisory Panel (SAP) (a committee of scientific experts from outside EPA). Based on these further reviews, OPP concluded that, although the accumulated evidence in humans implicated the phenoxy herbicides as potential risk factors, the evidence for 2,4-D alone was inadequate.

Furthermore, OPP determined that the oncogenicity studies submitted in response to the 1980 DCI did not achieve a maximum tolerated dose. Therefore, the studies were considered inadequate to assess the oncogenic potential of 2,4-D. The Agency has, however, since requested that the pathology slides be submitted for an independent evaluation before reaching a final conclusion regarding the acceptability of these studies.

Given that the available epidemiologic evidence and animal toxicological data were judged as inadequate to classify 2,4-D with respect to carcinogenicity, and in accordance with the Agency's Guidelines for Assessing Carcinogenic Risk, OPP classified 2,4-D as a Group D compound (not classifiable as to human carcinogenicity). The Carcinogen Assessment Group (CAG), of the Office of Research and Development (ORD), considered the epidemiologic evidence as stronger (limited evidence of human carcinogenicity) than did OPP but deferred its decision regarding the classification of 2,4-D until additional epidemiologic data are received and evaluated. The NCI has two other epidemiologic studies underway that will assess herbicides, in general, and 2,4-D specifically as to potential cancer associations. These studies are expected to be completed in the near future. CAG, OPP and other interested program offices will review the upcoming investigations to reach an Agency position on the carcinogenicity of 2,4-D.

The Agency also proposed that special review for 2,4-D, 2,4-DB, and 2,4-DP is not appropriate at this time (53 FR 9590, March 23, 1988). Final action will not be taken on this proposal until the Agency has reviewed the additional epidemiologic data and reached a conclusion regarding the oncogenicity studies.

In addition, as part of the Agency's strategy on dioxins, EPA issued a DCI Notice in June 1987 requiring registrants to analyze their 2,4-D products for certain halogenated dibenzo-p-dioxin or dibenzofuran (HDD and HDF) contaminants. This Notice was issued based on the Agency's assumption that, because of the chemical structure, class and certain manufacturing and processing conditions, 2,4-D products could be contaminated with HDDs or HDFs.

EPA has long recognized the potential public health and environmental significance of 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) which has lethal effects at exceptionally low doses to aquatic organisms, birds, and some mammals. It has been shown to be carcinogenic, teratogenic, and fetotoxic in experimental animals and is acnegenic in humans. EPA also recognizes the potential health significance of a variety of HDDs and HDFs that are structurally related to 2,3,7,8-TCDD. While 2,3,7,8-TCDD has not been found in 2,4-D at levels analyzed to date, structurally related HDD and HDF contaminants have been reported.

Draft protocols for analyzing the pesticide have been submitted. EPA is evaluating the proposed methods to determine whether they meet the requirements specified in the DCI Notice.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed available data submitted to support registration of 2,4-D products. The reviewed data are basically those studies available to the Agency as of February 20, 1987; in the case of toxicology data, all available data have been included. Based on the review of these data, EPA has reached the conclusions set forth in this Standard. A summary of those conclusions follows. Additional discussion is contained in the remainder of this Chapter.

1. When 2,4-D is formulated as an ester or amine, the physical characteristics, biological activity and fate in the environment may be affected. EPA has little or no data to evaluate the effects of the ester or amine forms of 2,4-D. Therefore, the data requirements imposed by this Standard include testing for the 2,4-D esters and amines as well as the acid.

2. OPP has classified 2,4-D as a Group D oncogen (not classifiable as to human carcinogenicity) because the existing data are not adequate to assess the carcinogenic potential of 2,4-D. Additional information and data are required before a final classification of 2,4-D can be determined.

3. While published data indicate that 2,4-D may be teratogenic, an acceptable rat study is negative. An additional study in rabbits is required.

4. Several instances of accidental human poisoning with 2,4-D through dermal exposure, which has resulted in severe neurotoxicity, have been reported. Data are required to assess the neurotoxicity of 2,4-D.

5. Residues of 2,4-D have been detected in groundwater, mostly from point sources. Although laboratory data demonstrate that 2,4-D is mobile in soils, its potential to contaminate groundwater is limited by its rapid rate of degradation and uptake by target plants. Additional data and a label warning are required.

6. Certain formulations of 2,4-D are highly toxic to fish and/or aquatic invertebrates. Other formulations, for which the Agency has data, are in the range of moderately toxic to practically nontoxic to nontarget organisms.

7. The Office of Endangered Species has determined that certain uses of 2,4-D may jeopardize the continued existence of endangered species or critical habitat of certain endangered species.

As a result of this review, the Agency has identified missing data necessary to further evaluate the environmental and human risks associated with the use of 2,4-D. These data must be submitted in order to maintain registration of products or to register new products containing 2,4-D. These data are listed in the Data Tables contained in Appendix I.

The Agency has also determined that certain label restrictions or revisions are necessary, in order for 2,4-D products to remain in compliance with FIFRA. The Labeling section of this Standard contains the specific language required for each of the statements.

B. TOXICOLOGICAL ASSESSMENT

This section discusses acceptable data available to the Agency for 2,4-D. From a toxicological standpoint, the acid and its inorganic salts can be considered essentially identical. The amines and esters, however, are significantly different and, lacking data to indicate otherwise, may be expected to have different qualitative and/or quantitative toxicological properties.

The major exposure to these compounds is during application. Considering the common 2,4-D moiety in each compound, it could be expected that the 2,4-D portion of each molecule would be released during use. Thus, exposure would be to 2,4-D regardless of which 2,4-D compound is used. This expectation has particular validity if it serves to identify a serious toxicological problem with 2,4-D. If, for example, such a problem is identified, it is likely that all 2,4-D compounds will share this toxicity. However, if such a problem is not identified with 2,4-D, this does not preclude the possibility that one or more of the organic amines and/or esters does have such a problem.

Toxicological data for the acid, and for each amine and ester, are considered necessary to determine if the toxicity of these organic amines and esters differ significantly from the acid and from each other, and whether these toxic effects constitute an unacceptable risk to applicators.

Except as noted, the studies discussed below pertain to the 2,4-D acid.

ACUTE TOXICITY STUDIES. 2,4-D acid is of low oral, dermal and inhalation toxicity (Toxicity Category III). It is not a dermal sensitizer. No data are available on eye and dermal irritation.

Acute studies are available on a manufacturing use product of 2,4-D diethanolamine salt. These studies show low toxicity (Toxicity Categories III and IV) for the oral, dermal, and inhalation routes of exposure and for dermal irritation. The compound is not a dermal sensitizer. Data show, however, that this compound produced signs of severe irritation and corneal ulcer which was not resolved 21 days after treatment and is, therefore, considered a Toxicity Category I compound for eye irritation.

Acute oral and dermal toxicity studies of the isooctyl and isobutyl esters of 2,4-D show a low order of toxicity (Toxicity Category III).

Acute oral data show the 2,4-D isopropyl ester to be a Toxicity Category II compound while dermal, inhalation and eye and dermal irritation studies show a low toxicity (Toxicity Categories III and IV). Isopropyl ester is not a dermal sensitizer.

Data on 2,4-D butoxyethyl ester show low toxicity (Toxicity Category III) for oral, dermal, inhalation and primary eye and dermal irritation. The compound was found to be a dermal sensitizer in two studies while a third indicated no dermal sensitization.

SUBCHRONIC TOXICITY STUDIES. Supplementary studies in rats and mice indicate that the most sensitive effect was in the kidneys. Effects consisted of increased homogeneity and altered tinctorial properties of the cytoplasm and decreased intracellular/intraluminal vacuolization in the cortex. The lowest observed effect level (LOEL) for both species was 1 mg/kg/day, the lowest dose tested.

CHRONIC TOXICITY/ONCOGENICITY STUDIES. In a two-year oncogenicity study in mice, effects were seen in absolute and relative kidney and adrenal weights at 15 mg/kg/day and 45 mg/kg/day, the highest dose tested. Histopathology revealed an increase in the mid- and high-dose groups in cytoplasmic homogeneity of the renal tubular epithelium due to a reduction of cytoplasmic vacuoles. The no observed effects level (NOEL) for systemic effects was 1 mg/kg/day and the LOEL was 15 mg/kg/day.

In a two-year chronic/oncogenicity study in rats, compound related effects (increased tubular brown pigment and vacuolization of the cytoplasm of the cortex) were observed in the kidneys of males and females. The LOEL for systemic effects was 5 mg/kg/day and the NOEL was 1 mg/kg/day.

A review of the one-year interim sacrifice data from the rat and mouse studies indicated minimal toxicity at the highest dose tested (45 mg/kg/day). Increased kidney weights were observed in the high dose male rats and high dose female mice but even fewer kidney effects were seen at the highest dose after 52 weeks than had been evident at the same dose in the subchronic studies.

Based on available information, the Agency believes that neither the rat nor the mouse study reached a maximum tolerated dose (MTD). However, the Agency believes an independent evaluation of the kidney slides is appropriate before reaching a conclusion regarding the acceptability of these studies.

TERATOLOGY STUDIES. A teratogenicity study in rats was negative for teratogenic effects at the highest dose tested, 75 mg/kg/day. In this study, the test compound was administered by gavage to Fischer 344 female rats on days 6-15 of gestation at doses of 0, 8, 25 or 75 mg/kg/day. Twenty seven to thirty females per group were pregnant. Maternal toxicity was not observed at the highest dose tested; fetotoxicity, consisting of delayed ossification, was seen at the highest dose tested. The NOEL was 25 mg/kg/day. An additional study in the rabbit is required.

A teratology study of 2,4-dichlorophenol, a metabolite of 2,4-D, showed no teratogenic effects at 750 mg/kg/day, the highest dose tested. In this study, the test compound was administered by gavage to Fischer 344 female rats on days 6-15 of gestation at doses of 0, 200, 375, or 750 mg/kg/day. Maternal toxicity, consisting of depressed weight gains, was observed at 750 and 375 mg/kg/day; the NOEL was 200 mg/kg/day. Fetotoxicity, identified as delayed ossification, was observed at 750 mg/kg/day; the NOEL was 350 mg/kg/day.

REPRODUCTION STUDIES. In a dietary two-generation reproduction study in rats, toxicity consisted of reduced pup weight at birth and during lactation at 20 mg/kg/day with a NOEL of 5 mg/kg/day. Toxic effects to the adult females consisted of statistically significant weight depression during the four weeks prior to sacrifice but after weaning the F_{2b} pups, at 20 mg/kg/day with a NOEL of 5 mg/kg/day. Histopathology identified kidney tubule degeneration in the adult F_0 males at 80 mg/kg/day and to a lesser degree in the adult F_0 and F_1 adult males dosed at 20 mg/kg/day, with a NOEL of 5 mg/kg/day. No effects were seen on fertility in the F_0 or F_1 males or females.

MUTAGENICITY AND METABOLISM STUDIES. No data are available on the mutagenic potential or metabolism of 2,4-D.

NEUROTOXICITY STUDIES. The only available neurotoxicity study, one performed with the dimethylamine salt of 2,4-D, did not show neurotoxic effects. This study, however, has significant deficiencies and cannot be used for evaluation of the chemical's neurotoxicity. Additional data are required.

HUMAN EXPOSURE

Epidemiology Studies. In a population-based case control study conducted by the National Cancer Institute in Kansas (NCI), a relationship was found between farm herbicide use (phenoxyacetic acids) and non-Hodgkin's lymphoma but not between herbicide use and soft tissue sarcoma or Hodgkin's disease.

Although the Agency has concluded that this study was well conducted and served as a good basis for a hypothesis of a non-Hodgkin's lymphoma and phenoxy herbicide association, the Agency has concerns about the study. Some of the key areas of concern are lack of appropriate controls, exposure to multiple chemicals and insufficient information on actual exposure to 2,4-D. Because of these numerous areas of uncertainty, the Agency has not finalized its position regarding 2,4-D as the causative agent in the non-Hodgkin's lymphoma cases. In addition, another NCI study, published in 1987, on 2,4-D use by farmers in Western Washington does not confirm the Kansas study's conclusions.

A number of other epidemiologic studies pertaining to 2,4-D were found inappropriate for assessing cancer risk for 2,4-D users. However, NCI has two other epidemiology studies underway which will assess herbicides in general and 2,4-D specifically as to potential cancer associations. These studies are expected to be completed in the near future.

Incident Reports. Accidental human poisoning with 2,4-D, which resulted in severe neurotoxicity, has been reported. Reports available to the Agency involve three individuals accidentally exposed to an unidentified 2,4-D ester formulation, one individual exposed to 2,4-D dimethylamine salt and another exposed to a formulation containing 5.4 percent picloram and 20.9 percent 2,4-D isopropanolamine. All reports involved dermal exposure; in each case, neuropathy was reported following the accidental exposure and most reported slow recovery with some irreversible damage.

Statistical reports available to the Agency covering mortalities, hospitalizations and physician-treated poisoning provide the following information on 2,4-D:

Mortalities - During the years all accidental deaths due to pesticides were counted (1961, 1969, 1973, 1974), there were no deaths attributed to 2,4-D.

Hospitalizations - Based on a 12 percent sample of the nation's hospitals, 2,4-D was estimated to have caused an average of 12 hospitalizations each year during 1971-76, or 0.4 percent of the total pesticide poisoning hospitalizations. During 1974, 2,4-D was associated with 0.1 occupational hospitalizations per 1 million pounds reported used in agriculture. The average ratio of poisonings for all pesticides was 0.9 cases per million pounds reported in use.

Physician-Treated Poisonings - California, the only state which enforces mandatory reporting of occupational pesticide incidents, reported an average of one physician-treated 2,4-D poisoning each year from 1980 through 1986. An additional 3.1 cases per year were reported as either due to skin or eye injury.

Worker Exposure. Studies from the published literature were reviewed to define worker exposure to 2,4-D.

Several factors were identified as affecting the exposure of workers handling 2,4-D. Work activities appeared to affect worker exposure, with mixer/loaders in general receiving higher exposures than workers performing application tasks. In addition, the use of protective clothing, particularly protective gloves, coupled with good hygienic practices appears to reduce worker exposure to 2,4-D. The contribution of respiratory exposure to total worker exposure was judged by all investigators who measured air concentrations of 2,4-D to be negligible, indicating that the dermal route accounts for the major portion of worker exposure. Amounts of 2,4-D excreted were also noted to be a function of the duration of exposure and the application rate.

The dermal exposures reported in these studies are as follows:

Application Site	Worker	Exposure
Aquatic	Applicator	12 ug/kg/lb ai applied
Pasture	Applicator	≤ 18 mg (hands)
Noncrop	Applicator	30-52 ug/ft treated
Grassland	Mixer/Loader	8-486 ug/operation
	Applicator	10-191 mg/hr
Forestry	Pilot	5 ug/kg[1] <0.1 ug/kg[2]
	Mixer/Loader	448 ug/kg[1] 22.2 ug/kg[2]

[1] With ordinary precautions

[2] With special precautions, including protective gloves

C. OTHER SCIENCE FINDINGS

ENVIRONMENTAL FATE. Available data are insufficient to fully assess the environmental fate of 2,4-D. An ester or amine derivative of 2,4-D may behave differently in the environment. Only after the ester or amine derivative of 2,4-D acid degrades into the acid moiety is general data on 2,4-D applicable. The Agency needs environmental fate data on each ester and amine as well as the acid itself.

The rate and completeness of the dissociation or degradation reaction are essential to the development of the environmental fate profile of each registered chemical covered under this Standard. The required data will enable the Agency to evaluate the process or processes involved in the degradation of the amine and ester derivatives of 2,4-D, as well as the fate of the degradates.

The only acceptable data available to the Agency is for the parent 2,4-D. Based on that data, the following conclusions can be made:

Under aerobic conditions, 2,4-D degrades rapidly in most soils and is mobile to highly mobile in sand, silt, loam, clay loam and sandy loam. However, in an aged residue study, 2,4-D was only slightly mobile. It appears that the compound has an affinity to bind with organic matter over time. The 2,4-D degradates of ester and amine forms of 2,4-D can also be expected to be mobile. The leaching potential of these

2,4-D degradates will be affected by the rate of its degradation of the ester and amine compounds and the binding capacity of the soil and rate of degradation of 2,4-D acid.

Supplemental data, which do not fulfill requirements for registration, indicate that residues of 2,4-D, per se, in water systems from aquatic application reach a maximum concentration within 1 day of application. These data indicate that residues dissipate rapidly in moving water; in still waters, such as ponds, lakes, and reservoirs, residues of 2,4-D, per se, were detected as much as 6 months after application. Supplemental octanol/water partition coefficient data indicate low potential for 2,4-D, per se, to accumulate in fish.

The Agency has no acceptable data on the ester or amine forms of 2,4-D. However, supplemental data indicate that the rate of degradation/dissociation of 2,4-D compounds to the parent acid is variable. Rapid rate of dissociation of dimethylamine salts and triethanolamine are reported. Additionally, in moving water, dissipation of all 2,4-D residues from addition of dimethylamine salt occurred in less than 1 day. Conversely, in ponds, lakes and reservoirs, residues of 2,4-D, per se, were detected in water as much as 6 months after treatment. In all cases, maximum 2,4-D concentrations in water were reached within 1 day and dissipated rapidly thereafter.

Data summarized from the Pesticide Incident Monitoring System, as reported below, indicate that 2,4-D is volatile and may adversely affect non-target crops.

Groundwater. Available laboratory data indicate that the parent 2,4-D is mobile in soils ranging in texture from sand to clay loam. 2,4-D has been detected in about 100 of at least 1700 samples of groundwater taken in nine states. Positive samples were found in six of these states. Most of the positive findings of 2,4-D in groundwater have been associated with point sources. The highest concentration found, believed to be from a point source, is 36.5 ppb (ug/L). The highest nonpoint source (i.e., normal use patterns and subsequent leaching) finding was 4.2 ppb with most findings being less than 1.0 ppb.

The potential of 2,4-D to contaminate groundwater under normal use conditions is limited by the rapid rate of degradation, by binding to organic material in the soil, and by uptake in the target plants. Limited data are available on the rates of degradation of the various 2,4-D compounds. The mobility of parent materials as well as rates of formation and decline of the resultant 2,4-D will affect the potential to contaminate groundwater.

Reentry. Based on available toxicological data, 2,4-D products are of low acute toxicity, generally falling in Toxicity Categories III and IV. Because of these levels of toxicity, reentry is not a concern.

Pesticide Incident Monitoring System (PIMS). Based on the PIMS files, covering the period 1966 to 1979, reports were received concerning the off-target movement of 2,4-D in unspecified formulations, esters and amines. The incidents involved drift from aerial (173 reports) and ground (104 reports) applications as well as volatilization and drift (35 reports) and resulted in damage to off-target crops or other desirable plants.

ECOLOGICAL EFFECTS. Available data are insufficient to completely evaluate the ecological effects of 2,4-D acid. Data, as set forth in the data tables, are either required or reserved pending further evaluation. However, the following conclusions can be made based on available data:

Effects on Birds. Of the data available to the Agency, only studies with 2,4-D acid and 2,4-D butyl ester are acceptable in support of registration. These data report toxicity values (LD_{50}s) of >2000 mg/kg (Mallards) and 472 mg/kg (Pheasant) for 2,4-D acid, which indicates moderately to practically nontoxic on an acute basis. Toxicity values (LC_{50}s and LD_{50}s) of 10000 ppm (Mallards), 12979 ppm (Bobwhite) and 4640 mg/kg (Mallards) are reported for the butyl ester, which may be characterized as practically nontoxic to avian species on an acute and chronic basis.

Effects on Fish. Based on studies available to the Agency, 2,4-D acid and certain of its salts, esters and amines can be characterized in the range of moderately toxic to practically nontoxic to fish. However, the compounds N-oleyl-1,3- propylenediamine salt, N,N-dimethyloleyl-linoleylamine, butyl ester, butoxyethanol ester and propylene glycol butyl ether ester can be characterized as highly toxic to fish. The toxicity values (LC_{50}s) reflected below are from acceptable studies performed with the technical grade of the test compound:

2,4-D acid	110 ppm (*Salmo gairdneri* [rainbow trout]) 180 ppm (*Lepomis machchirus* [bluegill sunfish]) 24.5-172 ppm (*Salmo clarki* [cutthroat trout]) 44.5-120 ppm (*Salvelinus namaycush* [lake trout])
Lithium salt	>180 ppm (bluegill sunfish)

Sodium salt	>100 ppm (rainbow trout)
Alkanolamine salt	>180 ppm (bluegill sunfish and rainbow trout)
Butyl ester	0.49-2.82 ppm (cutthroat trout)
	0.5-2.8 ppm (lake trout)
	0.4-0.96 ppm (rainbow trout)
	0.29-0.3 ppm (bluegill sunfish)
Isooctyl ester	19.5 ppm (bluegill sunfish)
	96 ppm (rainbow trout)
Propylene glycol butyl ether ester	0.33-2.8 ppm (cutthroat trout)
	0.39-2.93 ppm (lake trout)
	0.95-1.44 ppm (rainbow trout)
	0.56-0.67 ppm (bluegill sunfish)

The toxicity values (LC_{50}s) reflected below are from acceptable studies performed with a formulated product:

Alkylamine salt	3.93-9.4 ppm (bluegill sunfish)
	6.1-15.7 ppm (rainbow trout)
Diethanolamine salt	1030 ppm (rainbow trout)
Dimethylamine	>100-395 ppm (*Ictalurus punctatus* [channel catfish])
	>100-420 ppm (rainbow trout)
	266-800 ppm (*Pimephales promelus* [fathead minnow])
	>100-335 ppm (bluegill sunfish)
Isopropylamine salt	1700 ppm (bluegill sunfish)
	2840 ppm (rainbow trout)
	2231 ppm (fathead minnow)
N-oleyl-1,3-propylenediamine salt	0.3 ppm (bluegill sunfish)
	0.8 ppm (channel catfish)
Octylamine salt	28 ppm (bluegill sunfish)
N,N-dimethyloleyl-linoleylamine	0.64 ppm (rainbow trout)
Butoxyethanol ester	0.65 ppm (rainbow trout)
	0.76-1.2 ppm (bluegill sunfish)
	3.3 ppm (fathead minnow)
	0.78-1.35 ppm (channel catfish)
Butoxypropyl ester	5.4 ppm (rainbow trout)
Isooctyl ester	51-64 ppm (rainbow trout)
Propylene glycol butyl ether ester	0.8 ppm (bluegill sunfish)

Partially acceptable studies for 2,4-D heptylamine salt are available; these studies did not report percent of active ingredient of the test material. Toxicity values (LC_{50}s) reported are 15 ppm (bluegill) and 4.7 ppm (rainbow trout).

Effects on Freshwater Invertebrates. Based on data available to the Agency, dimethylamine, isooctyl ester, butoxyethanol ester and propylene glycol butyl ether ester forms of 2,4-D can be characterized as highly toxic to aquatic invertebrates. Data available on other 2,4-D compounds indicate toxicity in the range of slightly toxic to practically nontoxic.

Studies with the propylene glycol butyl ether ester were performed with a technical grade of the compound. The toxicity values (LC$_{50}$s) from these studies are 0.1-14 ppm (*Daphnia magna*); 4.9 ppm (*Simocephalus serrulatus*); and 0.42 ppm (*Cypridopsis vidua*).

The toxicity values (LC$_{50}$s) reflected below are from acceptable studies performed with a formulated product:

Alkylamine salt	3.26 ppm (*Daphnia magna* [waterflea])
	2.38 ppm (*Hyalella* [scud])
Dimethylamine	4.0->100 ppm (waterflea)
	>100 ppm (*Gammarus fasciatus* [side swimmer])
	>100 ppm (*Chironomus plumosus* [midge])
Isopropylamine salt	583 ppm (waterflea)
Butyl ester	2.8 ppm (waterflea)
Isooctyl ester	0.5 ppm (waterflea)
Butoxyethanol ester	1.7-6.4 ppm (waterflea)
	2.2 ppm (*Cypridopsis vidua* [seed shrimp])
	2.6 ppm (*Asellus brevicaudus* [sow bug])
	0.44-6.1 ppm (side swimmer)
	0.39-0.79 ppm (midge)

In addition, a study using a 2,4-D dimethylamine formulated product on *Paleamonetes kadiakensis* (grass shrimp) reported an LC$_{50}$ of 0.15 ppm. This study does not satisfy requirements for registration because the test species is not a recommended species and mature individuals were used. The study, however, is a valid study.

Effects on Estuarine and Marine Organisms. Acceptable data are available only for a formulated product of 2,4-D butoxyethanol ester. These data report toxicity values (LC$_{50}$s) of 5.0 mg/L (*Fundulus similis* [longnose killifish]), 2.6 mg/L (*Crassostrea virginica* [Eastern oyster]) and 5.6 mg/L (*Penaeus aztecus* [brown shrimp]), which indicate that the material is moderately toxic to estuarine and marine organisms.

Effects on Plants. Limited plant protection studies are available.

In a spray drift study, two application methods were compared as to quantity and pattern of deposition. No difference was found between the amine derivatives (diethanolamine and dimethylamine). With these amines, drift was observed beyond 225 feet from the site of application. No residues, attributable to drift, were found when applied postemergent to wheat or corn.

The toxicity of butoxyethanol ester was tested on four species of algae, using a formulated product. The toxicity values (EC_{50}s) were 75 mg/L (*Isochrysis galbana*, *Dunaliella tertiolecta* and *Chlorococcum sp.*) and 150 mg/L (*Phaeodactylum tricornutum*).

Risks to Nontarget Organisms (Including Endangered Species). Because of limited environmental fate and ecological effects data, complete hazard assessments cannot be conducted at this time.

Because of its demonstrated toxicity to nontarget species and its intended use pattern, this pesticide has been identified by the Office of Endangered Species (OES), U.S. Fish and Wildlife Service, as being likely to jeopardize the continued existence of certain endangered species when used on range, pastureland, corn, wheat, sorghum, oats, barley, and/or rye. Based on this determination, OES specified reasonable and prudent alternatives to avoid jeopardizing the continued existence of the identified species by these uses. EPA is working with the Fish and Wildlife Service and other Federal and State agencies to implement the alternatives in a technically sound manner.

Nontarget Insects. There is sufficient information to characterize 2,4-D as relatively nontoxic to honey bees, when bees are exposed to direct treatment.

PRODUCT CHEMISTRY. EPA has evaluated the available data which identify the ingredients, materials, and manufacturing process and provide information on the physical and chemical properties of 2,4-D.

The Agency has noted that 2,4-D may be contaminated with tetra- through heptahalogenated dibenzo-p-dioxins or dibenzofurans or N-nitrosamines. Certain polyhalogenated dibenzo-p-dioxin or dibenzofuran congeners have been found to be mutagenic, oncogenic, teratogenic and to cause reproductive toxicity. Nitrosamines have been found to be oncogenic. Analytic data to identify and quantify tetra- through hepta-chlorinated dibenzo-p-dioxin or dibenzofuran contaminants were required in a Data Call-in Notice issued in June 1987. Analytic data to identify and quantify N-nitrosamines are being required, as specified in the data tables.

D. TOLERANCE ASSESSMENT

Tolerances and food and feed additive regulations have been established for residues of 2,4-D in a variety of raw agricultural commodities and meat byproducts (40 CFR 180.142), and in processed food (40 CFR 185.1450) and feed (40 CFR 186.1450). EPA has evaluated the residue and toxicology data supporting these tolerances. The following were considered during this evaluation:

- Whether the current tolerances and food additive regulations are sufficient to cover the actual residues resulting from use (including FIFRA section 24(c) and intrastate uses).
- Whether group tolerances can be established in accordance with 40 CFR 180.34(f).
- Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.
- Whether the tolerances are expressed accurately and in current terminology.

The regulatory results of the Agency's review are set out in the Regulatory Positions and Rationale section.

Residue Data. The residue data reviewed in support of these tolerances include the following:

1. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of 2,4-D. The nature of the residue is not adequately understood.
2. Analytical methodology for determining the levels of residues of 2,4-D in plants and animals. Available methods are adequate only for collection of data pertaining to residues of 2,4-D, per se, on most plant and animal commodities.
3. Storage stability data. These data demonstrate that residues of 2,4-D, per se, in potatoes are stable for up to 73 weeks when stored at -20°C. Additional data are required.

4. Data on the magnitude and levels of residues of 2,4-D, per se, in individual raw agricultural commodities, animal products, and processed food and feed items. Data are not adequate to support all of the established tolerances.

Toxicology Data. A provisional acceptable daily intake (PADI) of 0.003 mg/kg/day for 2,4-D acid has been established based on a two-year rat feeding study. Compound-related effects were observed in the kidneys of both male and female rats. The LOEL was 5 mg/kg/day and the NOEL was 1 mg/kg/day. An uncertainty factor of 100 was used to account for the inter- and intraspecies differences. An additional uncertainty factor of 3 was used since there is no dog study available and no information available that indicates the dog is less sensitive than the rat.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on the review and evaluation of available data on 2,4-D, the Agency has made the following determinations. Where label revisions are imposed, specific language is set forth in the Labeling section of this chapter.

1. The Agency will not place 2,4-D in special review at this time.

   Rationale. In September 1986, based on epidemiologic evidence available at that time, the Agency issued a preliminary notification of special review to the registrants of 2,4-D. Based on additional evaluation of this evidence and other toxicological data, the Agency subsequently concluded that these data were inadequate to assess the oncogenic potential of 2,4-D. Therefore, in March 1988, EPA proposed not to initiate a special review of the chemical at this time.

   The Agency's concerns regarding the toxicological effects of 2,4-D have not been fully resolved. Additional epidemiological studies are expected to be completed soon and additional laboratory studies are required by this Standard. As these data become available, the Agency will further evaluate the potential risks of 2,4-D and could initiate a special review at a later time and/or consider additional regulatory action, if applicable.

2. The Agency will not restrict the use of 2,4-D products to certified applicators.

   Rationale. Based on available data, 2,4-D products have not met or exceeded any of the criteria specified in 40 CFR 152.170 which would indicate a need to restrict its use.

3. The Agency will require data on the salts, amines and esters of 2,4-D as well as the acid, as reflected in the data tables.

   Rationale. When 2,4-D is formulated as an ester or amine, the physical characteristics, biological activity and fate in the environment may be affected. The Agency has little or no data to evaluate the effects of the ester or amine derivative of 2,4-D. Data on each salt, ester and amine derivative are needed to allow evaluation of these forms of 2,4-D.

4. The Agency will not consider establishment of significant new food use tolerances for 2,4-D.

Rationale. The current residue chemistry and toxicology data are not sufficient to assess existing and pending tolerances. In addition, the Agency has concerns about the human carcinogenicity of this chemical. Therefore, the Agency will not consider any significant new uses until data are available to resolve these issues.

5. The Agency is requiring additional data, as set forth in the data tables, to support established tolerances.

   Rationale. Existing data are insufficient to support established tolerances, as specified in the data tables.

6. The Agency will assess the adequacy of the tolerances for residues of 2,4-D in meat, milk, poultry, eggs, fish and shellfish, upon receipt and evaluation of required metabolism data.

   Rationale. Data are unavailable to ascertain the adequacy of these tolerances.

7. The Agency will require that tolerances be proposed and appropriate supporting data be submitted for oat hay, flaxseed, flax straw, alfalfa, ladino clover, non-grass animal feeds, and avocados. In lieu of proposing tolerances and submitting supporting data, registrants may delete these uses from the label or, for oat hay, add feeding restrictions to the label. Registrants have 3 months to notify the Agency of which option they choose.

   Rationale. Tolerances have not been proposed or established for residues of 2,4-D that occur from its use on these commodities.

8. The Agency is requiring registrants to amend label directions for products registered for use on pastures and rangeland grasses and to propose label amendments to clarify the uses of 2,4-D on certain other raw agricultural commodities.

   Rationale. Directions on labels of products registered for use on grass hay do not contain the appropriate pregrazing, preharvest and preslaughter intervals supported by data available to the Agency. Labels of products registered for use on certain other raw agricultural commodities do not provide sufficient information regarding preharvest intervals, applications rates, allowable ranges of diluent for treatment, etc.

9. Pending submission of analytical method validation data and the results of water degradation/metabolism studies, the Agency will delete obsolete crop groupings and establish a

single tolerance of 1 ppm for 2,4-D residues resulting from use of irrigation water containing up to 0.5 ppm in or on members of crop groups listed in 40 CFR 180.34 and individual miscellaneous commodities. If additional degradates/metabolites of toxicological concern are observed in the water degradation/metabolism studies, additional residue data on irrigated crops will be required.

Rationale. Data submitted for various irrigated crops indicate the level of 2,4-D per se residues expected in irrigation water as a result of aquatic use on ponds, lakes and reservoirs is 0.5 ppm.

10. The Agency will propose the following technical changes in the listing of 2,4-D tolerances: (i) the commodity entry "nuts" will be amended to "tree nuts;" (ii) the commodity entry "millet forage and straw" will be deleted; and (iii) the commodity entry "millet grain" will be amended to "millet grain, proso."

    Rationale. These technical changes are required because (i) "tree nuts" is the appropriate commodity definition; (ii) millet forage and straw are not considered raw agricultural commodities of millet; and (iii) the addition of "proso" clarifies the tolerance statement for millet grain.

11. The Agency will:

    (1) eliminate the following 2,4-D derivatives from the tolerance expression: alkyl (C-13), alkyl (C-14), amylamine, diisopropanolamine, ethylamine, linoleylamine, methylamine, oleylamine, propylamine, trimethylamine, amyl (pentyl), butoxypolythylene glycol butyl ether, dipropylene glycol isobutyl ether, ethoxyethoxyethyl, ethoxyethoxypropyl, ethyl, ethoxypropyl, methyl, polyethylene glycol 200, polypropoxybutyl, polypropylene glycol, propylene glycol, propylene glycol isobutyl ether, tetrahydrofurfuryl and tripropylene glycol isobutyl ether;

    (2) revoke the tolerance of 5 ppm for residues of 2,4-D in or on quinces, and the tolerance for residues of 2,4-D in or on apricots, resulting from the appli- cation of dimethylamine salt; and

    (3) revise the tolerance statement for use on citrus fruits to include the 2,4-D triethanolamine salt.

    Rationale. There are no registered uses for the above listed derivatives of 2,4-D; for quinces; or for 2,4-D dimethylamine salt in apricot orchards apart from the general use on stone fruits. Therefore, these tolerances are unnecessary. There are registered uses for the 2,4-D triethanolamine salt on citrus fruits and it should be a part of the tolerance statement.

12. The Agency will revoke the food additive regulation of 0.1 ppm for residues of 2,4-D in potable water.

    Rationale. The Agency no longer establishes tolerances for pesticides in potable water but rather sets maximum contaminant levels (MCLs) in drinking water. An MCL of 0.1 mg/L is currently established for 2,4-D in drinking water.

13. The Agency is requiring precautionary labeling to minimize any potential hazard to nontarget organisms.

    Rationale. Certain formulations of 2,4-D are highly toxic to fish and/or aquatic invertebrates. Precautionary labeling will reduce any potential risks to these organisms from the use of 2,4-D.

14. The Office of Endangered Species (OES) in the U.S. Fish and Wildlife Service has determined the use of 2,4-D may jeopardize the continued existence of endangered species or critical habitat of certain endangered species. EPA is developing a program to reduce or eliminate exposure to these species to a point where use does not result in jeopardy, and will issue notice of any necessary labeling revisions when the program is developed. No additional labeling is being required at this time. As explained below, labeling requirements issued in Pesticide Regulation (PR) Notices 87-4 and 87-5 have been withdrawn.

    Rationale. In May 1987, EPA issued PR Notices 87-4 and 87-5 in response to OES findings that certain pesticides, including this chemical, jeopardized the continued existence of endangered species. Those PR Notices directed registrants to add labeling to their products which referred users to additional information that, in turn, explained limitations on use of the pesticide within the range of jeopardized endangered species. Subsequent to issuance of these PR Notices, EPA identified a number of significant technical errors and inconsistences in the information to which users would have been referred. Therefore, on January 26, 1988, the Agency issued PR Notice 88-1 which withdrew PR Notices 87-4 and 87-5 pending development of a more focused program to protect endangered species.

    EPA is working to correct these errors prior to requiring labeling to protect endangered species. When that program is fully developed, notice of any labeling necessary to protect endangered species will be issued.

15. The Agency is requiring a groundwater warning statement on the labels of 2,4-D products.

Rationale. Although laboratory data demonstrate that 2,4-D is mobile in soils, its potential to contaminate groundwater is limited by its rapid rate of degradation and uptake by target plants. However, residues of 2,4-D have been detected in groundwater, mostly from point sources, such as mixing, loading and disposal. Since 2,4-D could be a potential groundwater contaminant, a label statement will advise users to exercise caution when handling 2,4-D products to prevent such contamination.

The Agency is currently finalizing its Agricultural Chemicals in Groundwater Strategy and its policy for restricting the use of pesticide products which may reach groundwater. When the policies are in place, the Agency will consider what action is appropriate for 2,4-D products and other products containing ingredients which may reach groundwater.

16. The Agency is not requiring a reentry interval for 2,4-D products.

Rationale. Based on the toxicological data available to the Agency, 2,4-D products are of low toxicity (Toxicity Categories III and IV). Because of these low toxicity levels, it is not considered necessary to establish a reentry interval.

17. The Agency is requiring protective clothing (gloves) labelling for end-use products.

Rationale. Based on the available data, the major route of exposure to workers handling 2,4-D is dermal and reported incidents of accidental poisoning involve dermal exposure. This exposure can be reduced through the use of protective gloves. The use of gloves while handling 2,4-D products will reduce lower exposure.

18. The Agency is requiring special neurotoxicity studies.

Rationale. Several instances of accidental human poisoning from dermal exposure to 2,4-D formulations, which resulted in neurotoxicity, have been reported. Data are required so that the Agency can evaluate the chemical's neurotoxicity.

19. EPA is requiring analytical chemistry data for 2,4-D products to evaluate contamination with tetra- through heptahalogenated dibenzo-p-dioxins or dibenzofurans or N-nitrosamines.

Rationale. Polyhalogenated dibenzo-p-dioxins or dibenzofurans may be formed during manufacture of 2,4-D and N-nitrosamines may be formed during manufacture or storage of 2,4-D. The Agency has identified these contaminants as being toxicologically significant. The Agency does not have sufficient data to determine the extent and significance of the contamination.

20. The Agency will immediately review certain data as they are submitted.

Rationale. Because of concerns regarding potential risks from 2,4-D use, the Agency believes it is essential that the following data be reviewed as they are received: all toxicological studies; spray drift data; plant and animal metabolism studies and validation methods; and dioxin, furan and nitrosamine analysis and octanol/water partition coefficient data.

21. While data gaps are being filled, currently registered manufacturing-use products (MP's) and end-use products (EP's) containing 2,4-D may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. However, significant new uses will not be registered. Registrants must provide or agree to develop additional data, as specified in the data tables, in order to maintain existing registrations.

Rationale. Under FIFRA, the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)). Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary. Because of the quantity of data required to maintain existing registrations, the Agency has elected not to consider registration of any significant new uses while data gaps are being filled and data evaluated.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain this pesticide, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

C. ACCEPTABLE RANGES AND LIMITS

Product Composition Standard. To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain this pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

Acute Toxicity Limits. The Agency will consider registration of technical grade and manufacturing-use products containing this pesticide provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

Use Patterns. To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products bearing federally registered uses. The EPA Index to Pesticide Chemicals (for availability, see page 1) lists all federally registered uses of this pesticide ingredient, as well as approved maximum application rates and frequencies.

The use patterns currently registered are terrestrial (food and nonfood); aquatic (food and nonfood); domestic; and forestry.

D. LABELING

All products must bear appropriate labeling as specified in 40 CFR 156.10, PR Notices 83-2, 83-3, and below. Appendix II contains further information on label requirements.

Time Frames for Compliance. Pesticide products containing this pesticide as an active ingredient may not be released for shipment by the registrant after October 1, 1989, unless the product bears amended labeling that complies with the requirements of FIFRA, as set out in this Registration Standard.

Pesticide products containing this pesticide as an active ingredient may not be distributed or sold by any person after October 1, 1990, unless the product bears amended labeling that complies with the requirements of this Standard.

In addition to the above labeling requirements, the following information must appear on the labeling of all manufacturing use and end use products.

Ingredient Statement. The ingredient statement for MP's must list the active ingredient as:

2,4-Dichlorophenoxyacetic Acid . . . . ___ %

OR

(Applicable salt, amine or ester) . . . . ___ %
2,4-Dichlorophenoxyacetic Acid Equivalent: ___

Use Pattern Statements. All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

Disposal Statements. Certain unused 2,4-D stocks are listed as toxic hazardous waste under the Resource Conservation and Recovery Act (RCRA); others may be hazardous waste because of their chemical physical characteristics. The following is the appropriate pesticide disposal statement for all 2,4-D products, except those labeled for household use only:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate, is a violation of Federal Law and may contaminate groundwater. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Products labeled for household use only must bear the following disposal statement:

> "Securely wrap original container in several layers of newspaper and discard in trash."

The labels of all products must bear the appropriate container disposal statement (see Appendix II).

Precautionary Statements

1. For all 2,4-D products, except those listed below in items 2 and 3, the following precautionary statements are required.

Manufacturing-Use Products

> "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do

not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

End-Use Products

Aquatic Uses. "Drift or runoff may adversely affect nontarget plants. Do not apply directly to water except as specified on this label. Do not contaminate water when disposing of equipment washwaters."

Nonaquatic Uses. "Drift or runoff may adversely affect nontarget plants. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters."

2. The following precautionary statements are required for end-use products containing the following 2,4-D derivatives:

N-oleyl-1,3-propylenediamine salt
N,N-dimethyloleyl-linoleylamine
Butyl ester
Butoxyethanol ester
Propylene glycol butyl ether ester

Manufacturing-Use Products

"This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

End-Use Products

Aquatic Uses. "This product is toxic to fish. Drift or runoff may adversely affect fish and nontarget plants. Do not apply directly to water except as specified on this label. Do not contaminate water when disposing of equipment washwaters."

Nonaquatic Uses. "This product is toxic to fish. Drift or runoff may adversely affect fish and nontarget plants. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters."

3. The following precautionary statements are required for end-use products containing the following derivatives of 2,4-D.

Dimethylamine
Isooctyl ester

Manufacturing-Use Products

"This product is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

End-Use Products

Aquatic Uses. "This product is toxic to aquatic invertebrates. Drift or runoff may adversely affect aquatic invertebrates and nontarget plants. Do not apply directly to water except as specified on this label. Do not contaminate water when disposing of equipment washwaters."

Nonaquatic Uses. "This product is toxic to aquatic invertebrates. Drift or runoff may adversely affect aquatic invertebrates and nontarget plants. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters."

4. All End-Use Products. The following statements are required in the use directions for all end-use products:

End-Use Products - Liquid

"This product can reach groundwater as a result of mixing and loading. To minimize groundwater contamination from spills during mixing, loading and cleaning of equipment, take the following steps:

"Mixing and Loading: When mixing, loading or applying this product, wear chemical resistant gloves. Wash nondisposable gloves thoroughly with soap and water before removing.

"The mixing and loading of spray mixtures into the spray equipment must be carried out on an impervious pad (i.e., concrete slab, plastic sheeting) large enough to catch any spilled material. If spills occur, contain the spill by using an absorbent material (e.g, sand, earth or synthetic absorbent). Dispose of the contaminated absorbent material by placing in a plastic bag and following disposal instructions on this label.

"Triple rinse empty containers and add the rinsate to the mixing tank.

"Cleaning of Equipment: When cleaning equipment, do not pour the washwater on the ground; spray or drain over a large area away from wells and other water sources."

End-Use Products - Granular

"This product can reach groundwater from improper handling. To minimize groundwater contamination from spills during loading and cleaning of equipment, take the following steps:

"Handling: When handling this product, wear chemical resistant gloves. Wash nondisposable gloves thoroughly with soap and water before removing. If spills occur, collect the material and dispose of by following disposal instructions on this label.

"Cleaning of Equipment: When cleaning equipment, do not pour the washwater on the ground; spray or drain over a large area away from wells and other water sources."

5. End-Use Products - Use on Pastures and Rangeland Grasses. Labels for products registered for use on pastures and rangeland grasses must be revised to reflect the following intervals, if such intervals are not currently on the label:

a. A 7-day pregrazing interval for dairy cattle;

b. A 30-day preharvest interval for grass cut for hay; and

c. A preslaughter interval for meat animals of 3 days.

6. End-Use Products - Certain Food/Feed Uses. Label use directions for products registered for the following uses must be revised: potatoes, apples, pears, grapes, strawberries, barley and barley forage, corn and corn forage and fodder, millet, oats, rice and rice straw, rye, sorghum and sorghum forage and fodder, wheat, rangeland and pasture grass, asparagus, and sugarcane. The revisions pertain to preharvest intervals, ranges of diluent, and maximum seasonal application rates and/or number of applications. The data tables contain specific requirements for each commodity. The registrants must propose the specific language. Since these revised use directions must be reflective of data required by this Standard, time frames for these requirements will coincide with the time frames for submission of data.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

  1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
  2. The data requirements listed in Tables A and B.[2]
  3. The labeling requirements specified for manufacturing use products in Section IV.
  4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

  1. The data requirements listed in Table A.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

    2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

    1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

    2. If eligible for the generic data exemption,[3] the data requirements listed in Table C.

    3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

    4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

    1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

    2. If eligible for the generic data exemption, the data requirements listed in Table C.

    3. The labeling requirements specified for end use products in Section IV.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to

join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer

must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment

Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELS

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: [Name of chemical] Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

   a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

   a. Application for Pesticide Registration (EPA Form 8570-1).

   b. Two copies of any required product-specific data (See Table B).

   c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

> Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.
>
> Table B contains product-specific data requirements that apply only to a manufacturing use product.
>
> Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food

E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data

requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 6 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation[1]	Must Additional Data Be Submitted?	Timeframe for Submission[2]
Part 158 Subpart C - Product Chemistry					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No	N/A	Yes[3]	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	No	N/A	Yes[4]	6 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	TGAI	No	N/A	Yes[5]	12 Months
Physical and Chemical Characteristics[6]					
63-2 - Color	TGAI	No	N/A	Yes	6 Months
63-3 - Physical State	TGAI	No	N/A	Yes	6 Months
63-4 - Odor	TGAI	No	N/A	Yes	6 Months
63-5 - Melting Point	TGAI	No	N/A	Yes[7]	6 Months
63-6 - Boiling Point	TGAI	No	N/A	Yes[8]	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation[1]	Must Additional Data Be Submitted?	Timeframe for Submission[2]
Part 158 Subpart C - Product Chemistry					
Physical and Chemical Characteristics (Continued)					
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No	N/A	Yes	6 Months
63-8 - Solubility	TGAI or PAI	No	N/A	Yes	6 Months
63-9 - Vapor Pressure	TGAI or PAI	No	N/A	Yes	6 Months
63-10 - Dissociation constant	TGAI or PAI	No	N/A	Yes	6 Months
63-11 - Octanol/water partition coefficient	PAI	No	N/A	Yes[9]	6 Months
63-12 - pH	TGAI	No	N/A	Yes[10]	6 Months
63-13 - Stability	TGAI	No	N/A	Yes	6 Months
Other Requirements:					
64-1 - Submittal of samples	N/A	N/A	N/A	N/A	N/A

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Part 158
Subpart C - Product Chemistry

[1] Not applicable. Although product chemistry data may been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

[2] Data must be submitted within the indicated timeframes, which begin on receipt of the Guidance Document.

[3] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

[4] A detailed discussion of all impurities that are or may be present at $\geq$ 0.1 percent, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This discussion must also address the possible formation of N-nitrosamines (amine formulations) and dibenzo-p-dioxins and dibenzofurans occurring in 2,4-D acid, salts and esters. Data submitted in response to the Data Call-In (DCI) Notice for analytical chemistry data on polyhalogenated dibenzo-p-dioxins/dibenzofurans in 2,4-D acid and its salts and esters may also partially fulfill this data requirement. These data are due as specified in the DCI Notice.

[5] Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

[6] Physicochemical characteristics as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

[7] Data needed if the technical product is a solid at room temperature.

[8] Data required if the technical product is a liquid at room temperature.

[9] Data required if the technical product is organic and nonpolar.

[10] Data required if the test substance is dispersible in water.

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.240 Residue Chemistry					
171-4 - Nature of the residue (Metabolism) - Plants	PAIRA	Partially	00004666, 00004667, 00004669, 00004675, 00004676, 00004677, 00004680, 00004681, 00004682, 00004683, 00004689, 00004693, 00004698, 00004699, 00004715, 00004723, 00004960, 00004996, 00074214, 00074215, 00074216, 00074217, 00102675, 00102676, 00102679, 00102717, 00123973, 40595701, 40600202,	Yes[2]	18 Months
171-4 - Nature of the residue (Metabolism) - Livestock	PAIRA and plant metabolites	Partially	00004705, 00068891	Yes[3,4]	18 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.240 Residue Chemistry (continued)					
171-4 - Residue analytical methods	TGAI and metabolites	Partially	00004701, 00004707, 00004719, 00004720, 00033119, 00035913, 00036171, 00037169, 00042288, 00045364, 00045365, 00046125, 00046185, 00055485, 00059025, 00059026, 00059027, 00059033, 00060113, 00060120, 00060870, 00060872, 00060880, 00061012, 00061014, 00061016, 00061017, 00061018, 00061645, 00066156, 00067425, 00068011, 00068892, 00068893, 00071787, 00074219, 00075198, 00075715, 00075716, 00075719, 00088176, 00102605, 00102710, 00102713, 00102714, 00102717, 00102719, 00102760, 00102815, 00102816, 00102821, 00102862, 00102865, 00109535, 00115499, 00115509	Yes[5,6,7]	15 months

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.240 Residue Chemistry (continued)					
171-4 - Residue analytical methods			00043278, 00115515, 00115741, 00115745, 00120057, 00121711, 00121733, 00123269, 00126684, 00127273, 00133938, 00136845, 00136848, 00139511, 00139951, 00140032, 00140092, 00156264, 40595702, 40595803, 40595804, 40600201,		
171-4 - Storage stability	TEP and metabolites	Partially	00035913, 00136845 00139511, 00140092 00145248	Yes[8]	15 Months
171-4 - Magnitude of the residue in plants[9]					
Root and Tuber Vegetables Group[10]					
- Potatoes	TEP	Partially	00060876, 00102814 00102862, 00136845	Yes[11] Yes[12]	18 Months 24 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.240 Residue Chemistry (continued)					
Citrus Fruits	TEP	Partially	00042526, 00102605, 00102737, 00102879, 00115509, 00139059, 00163903	Yes[13,14]	18 Months
Pome Fruits Group[15]					
- Apples	TEP	Partially	00102824	Yes[16] Yes[17]	18 Months 24 Months
- Pears	TEP	Partially	00102824	Yes[18]	18 Months
Stone Fruits Group	TEP	Partially	00088176	Yes[19] Yes[20]	18 Months 24 Months
Small Fruits and Berries Group[21]					
- Blueberries	TEP	Partially	00061010, 00061012	Yes[22]	18 Months
- Cranberries	TEP	Partially	00061010, 00061012	Yes[23,24,25]	18 Months
- Grapes	TEP	Partially	00061012, 00102833	Yes[26] Yes[27]	18 Months 24 Months
- Strawberries	TEP	Partially	00102717, 00102812	Yes[28]	18 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.240 Residue Chemistry (continued)					
Tree Nuts Group	TEP	Partially	00088176, 00115509	Yes[29,30]	18 Months
Cereal Grains Group[31]					
- Barley	TEP	Partially	00004610, 00036168 00036169, 00036171 00059025, 00059027 00059029, 00060117 00061010	Yes[32,33]	18 Months
- Corn (field & fresh)	TEP	Partially	00021755, 00022329 00025383, 00030692 00030697, 00102865	Yes[34,35,36,37,38] Yes[39]	18 Months 24 Months
- Millet	TEP	Partially	00025330, 00161187	Yes[40,41] Yes[42]	18 Months 24 Months
- Oats	TEP	Partially	00036169, 00059028 00102816	Yes[43,44]	18 Months
- Rice	TEP	Partially	00004594, 00120057	Yes[45] Yes[46]	18 Months 24 Months
- Rye	TEP	No	N/A	Yes[47,48]	18 Months
- Sorghum	TEP	Partially	00102719, 00102889 00120057	Yes[49,50,51] Yes[52]	18 Months 24 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.240 Residue Chemistry (continued)					
- Wheat	TEP	Partially	00022622, 00036168, 00036170, 00036171, 00045369, 00046127, 00059029, 00060111, 00061010, 00078482, 00090361, 00127226, 00128778	Yes[53,54,55] Yes[56,57]	18 Months 24 Months
Forage, Fodder, and Straw of Cereal Grains Group[58]					
- Barley forage, hay and straw	TEP	Partially	00036168, 00036171, 00059025, 00059027	Yes[59]	18 Months
- Corn forage and fodder	TEP	Partially	00021755, 00022622, 00025383, 00030692, 00030697, 00073273, 00075715, 00075724, 00102865, 00127273, 00139511	Yes[60,61,62,63,64]	18 Months
- Oat forage, hay and straw	TEP	Partially	00059028	Yes[65,66]	18 Months
- Rice straw	TEP	Partially	00120057	Yes[67]	18 Months
- Rye forage	TEP	No		Yes[68]	18 Months
- Sorghum forage, fodder and hay	TEP	Partially	00102719, 00102889, 00120057	Yes[69,70,71]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.240 Residue Chemistry (continued)					
- Wheat forage, hay and straw	TEP	Partially	00022622, 00036168, 00078482, 00127273, 00128778	Yes[72,73,74]	18 Months
Grass Forage, Fodder and Hay Group					
- Grass, pasture and rangeland	TEP	Partially	00004485, 00028173, 00028200, 00042288, 00061010, 00063507, 00090360, 00102712, 00120057, 00138635, 00144791, 00147047	Yes[75,76,77,78]	18 Months
Miscellaneous Commodities					
- Asparagus	TEP	Partially	00025338, 00060870	Yes[79]	18 Months
- Pistachios	TEP	No	N/A	Yes[80]	18 Months
- Sugarcane	TEP	Partially	00030701, 00068889, 00079738, 00102640, 00102794, 00115793, 00127823	Yes[81]	18 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.240 Residue Chemistry (continued)					
171-4 - Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	Partially	00004701, 00004707, 00004719, 00059034, 00068892, 00068893, 00102713, 00102714, 00102719	Yes[82]	18 Months
171-4 - Magnitude of residue in potable water, irrigated crops, and fish	TGAI or plant metabolites	Partially	00028443, 00035913, 00038429, 00043280, 00043759, 00052597, 00055755, 00102760, 00102788, 00118549 00139511	Yes[83]	18 Months

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§158.240 Residue Chemistry Footnotes

[1] Data must be submitted within the indicated timeframes, which begin on receipt of the Guidance Document, except residue studies, which begin on receipt of the Agency's review of the metabolism studies.

[2] Data depicting the total terminal residue of ring-labeled [^{14}C]2,4-D in three representative, dissimilar crops (potatoes, a grain crop, and an orchard fruit crop) are required. Residues must be characterized in the raw agricultural commodities produced following application of formulated [^{14}C]2,4-D to the crops under conditions representing normal cropping practices. Exaggerated dosages may be necessary in order to have sufficient ^{14}C-residues present for characterization. ^{14}C-Residues must also be analyzed by analytical methods suitable for tolerance enforcement.

Footnotes (Continued)

[3] Metabolism studies characterizing the 2,4-D residues of concern in ruminants and poultry are required. Animals must be dosed orally for a minimum of 3 days with ring-labeled [^{14}C]2,4-D fed in the diet at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice a day during the dosing period. Animals must be slaughtered within 24 hours of the final dose. The distribution and identity of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using residue analytical methods for tolerance enforcement to ascertain that the methods are capable of adequately recovering and identifying all residues of concern.

[4] Data depicting the nature of 2,4-D residues in swine are also required if the required metabolism studies with ruminants and poultry reveal that the metabolism of 2,4-D in these animals differs from that in rats.

[5] Validation data must be submitted for all GLC analytical methods used to collect data in support of tolerances for 2,4-D in plant and animal commodities.

[6] The Pesticide Analytical Manual (PAM) Vol. I, Sec. 221 multiresidue procedure for chlorophenoxy acids will suffice for the testing of 2,4-D acid (and 2,4-D phenol) in or on raw agricultural commodities under the PAM Vol. I Multiresidue Protocols I-IV.

[7] The nature of the residue of 2,4-D in plants and in animals is not adequately understood. If the requested plant and animal metabolism studies reveal the presence of additional residues of concern in plant and/or animal commodities, additional validated methods for data collection and tolerance enforcement may be required.

[8] The storage conditions and intervals must be submitted for all samples used to provide data previously submitted and requested in this Standard to support the established tolerances for 2,4-D residues of concern in or on raw agricultural commodities. This information must be accompanied by data depicting the percent decline in 2,4-D residues under the storage conditions and for the intervals specified. Samples bearing field-weathered residues or fortified samples must be analyzed immediately after harvest or fortification and again after storage intervals that are equivalent to those reflected in all previously submitted and currently requested residue data. Storage conditions for the samples must reflect data submitted previously and in response to requirements of this Standard. The storage intervals selected must allow for reasonable unforeseen delays in sample analysis. Upon receipt of these data, the adequacy of the established tolerances for 2,4-D residues of concern in or on raw agricultural commodities will be reevaluated.

[9] Residue data may be required after receipt and evaluation of the toxicology data required for each amine and ester.

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Footnotes (Continued)

[10] If the registrant seeks a crop group tolerance the following additional data are required:

- Additional residue data and label amendments for uses on potatoes (see the requirements for potatoes for more details).
- Use directions must be proposed and appropriate residue data must be submitted for the additional representative group members carrots, radishes and sugarbeets.

[11] Data depicting 2,4-D residues of concern in or on red potatoes harvested at regular intervals following the last of two foliar applications of, in separate tests, representative 2,4-D low volatile ester EC formulations (butoxypropyl or isooctyl) at 0.06 lb ae/A/application in 5 gal of water/A at 7-day intervals, and the 2,4-D isopropyl ester 1 percent dust (D) formulation at 0.07 lb ae/A/application at 10-day intervals must be submitted. The registrants must propose label amendments establishing an appropriate PHI and specifying the allowable range of diluent/A for all formulations applied as a liquid spray, conditions that must be reflected in the data requested above. Tests must be conducted in CA (6%), ID (25%), ME (7%), MN (4%) or ND (6%) or WI (6%), and OR (7%) or WA (15%) representing ca. 80 percent of 1985 U.S. potato production.

[12] Data depicting the potential for concentration of 2,4-D residues in potato chips, granules or flakes, and wet and dry peel processed from potatoes bearing measurable weathered residues must be submitted. If residues concentrate in any of these commodities, appropriate food/feed additive regulations must be proposed.

[13] Data depicting 2,4-D residues of concern in or on grapefruit and oranges sampled the day of treatment and at regular intervals following postharvest treatment with a water-wax emulsion containing 500 ppm ae of a representative 2,4-D amine salt formulation and a 2,4-D isopropyl ester EC formulation. Tests must be conducted in CA and FL representing 93 and 98 percent of 1984-85 U.S. grapefruit and orange production, respectively.

[14] Data depicting 2,4-D residues of concern in dried pulp, oil, molasses and juice processed from oranges bearing measurable weathered residues must be submitted. If the data indicate a potential for residue concentration in any of these commodities, the registrants must propose appropriate food/feed additive regulations.

[15] If the registrant seeks a crop group tolerance the following additional data are required:

Footnotes (Continued)

°Additional residue data for apples and label amendments for uses on pears (see individual crops for more details).

°Data depicting 2,4-D residues of concern in or on pears harvested at regular intervals following the last of multiple, broadcast, directed postemergence applications applied at regular intervals in the minimum amount of water for good weed covergage of the following (in separate tests): a representative EC formulation containing 2,4-D acid, at 1.8 lb ae/A/application; and a representative EC formulation of an oil-soluble 2,4-D alkylamine salt at 2 lb ae/A. The registrants must propose label amendments establishing (i) appropriate PHIs, (ii) maximum seasonal application rates and/or number of applications, and (iii) allowable ranges of diluent for treatment, all of which must be reflected in the requested data. Tests must be conducted in CA(39%), NY (2%), OR (26%), and WA (30%), representing ca. 100% of the 1985 U.S. pear production.

[16] Data depicting 2,4-D residues of concern in or on apples harvested at regular intervals following the last of multiple, broadcast, directed postemergence applications applied at regular intervals in the minimum amount of water for good weed coverage of the following (in separate tests): a representative emulsifiable concentrate (EC) formulation containing 2,4-D acid, at 1.8 lb ae/A/application; and a representative EC formulation of an oil-soluble 2,4-D alkylamine salt at 2 lb ae/A must be submitted. The registrants must propose label amendments establishing (i) appropriate PHIs, (ii) maximum seasonal application rates and/or number of applications, and (iii) allowable ranges of diluent for treatment, all of which must be reflected in the requested data. Tests must be conducted in CA (8%), MI (14%), NY (14%) or PA (7%), and WA (26%), representing ca. 70 percent of 1985 U.S. apple production.

[17] Data depicting 2,4-D residues of concern in dry pomace and juice processed from apples bearing measurable weathered residues must be submitted. If the data indicate a potential for concentration of residues in any of these processed commodities, appropriate food/feed additive regulations must be proposed.

[18] For residue data requirements for pears see Pome Fruits Group footnote. Also, the registrants must propose label amendments establishing (i) appropriate PHIs, (ii) maximum seasonal, application rates and/or number of applications, and (iii) allowable ranges of diluent for treatment.

[19] Data depicting 2,4-D residues of concern in or on the representative crop group members cherries, peaches, and plums (fresh prunes) harvested 40 days following the last of two postemergence directed spray applications of, in separate tests, the 3.8 lb ae/gal Emulsifiable Concentrate Multiple Active Ingredient (EC MAI) formulation (9.5% 2,4-D acid plus 33.36% 2,4-D triethylamine salt) and the 3.8 lb ae/gal Soluble Concentrate/Liquid (SC/L) MAI

Footnotes (Continued)

formulation (16.3% 2,4-D diethanolamine salt plus 33.2% 2,4-D DMA salt) at 1.4 lbs ae/A/application (in 20 gal water/A must be submitted. Tests must be conducted in CA (9%), MI (51%) and OR (12%) or WA (14%) for cherries; in CA (69%), GA (4%) or SC (11%), and NJ (5%) for peaches; and in ID (9%), MI (22%) and OR (49%) or WA (20%) for plums (fresh prunes) representing ca. 90, 90, and 80 percent of 1985 U.S. production for the respective fruit crops.

[20] Data depicting residues of 2,4-D in or on prunes processed from plums bearing measurable, weathered residues must be submitted. If the data indicate a potential for residue concentration of residues during processing, an appropriate food additive regulation must be proposed.

[21] If the registrant seeks a crop group tolerance the following additional data are required:

- Additional data for blueberries, cranberries, grapes, and strawberries (see individual crops for details).
- Use directions must be proposed and appropriate residue data must be submitted for the additional representative group member blackberry or other Rubus spp.

[22] Data depicting 2,4-D residues of concern in or on blueberries harvested two years following application of a representative 2,4-D ester EC formulation in an aqueous solution containing 1 lb ae/50 gal/A must be submitted. Tests must be conducted in ME where this use is permitted.

[23] Data depicting 2,4-D residues of concern in or on cranberries harvested at normal crop maturity following a single broadcast application of a 2,4-D isooctyl (2-ethylhexyl) G formulation at 3.8 lb ae/A must be submitted. Application must be made in the spring after snow and ice have melted from dormant vines. Tests must be conducted in MA (48%) and WI (36%) representing ca. 80 percent of 1985 U.S. cranberry production.

[24] Data depicting 2,4-D residues of concern in or on cranberries harvested 30 days following a single postemergence foliar application of the 2,4-D DMA salt 78.9 percent crystalline (Cr) formulation at 0.39 lb ae/A in 130 gal of water/A must be submitted. Tests must be conducted in MA where this use is permitted under EPA SLN Reg. No. MA830003. Alternatively, the registrant may elect to cancel this use.

[25] Data depicting 2,4-D residues of concern in or on cranberries harvested following one postemergence directed application of the 3.77 lb/gal EC formulation of 2,4-D DMA salt diluted in water (1:2, 1.26 lb ae/gal of water) must

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Footnotes (Continued)

submitted. Application must be made manually with a soaked towel wrapped on a hockey stick to weeds growing taller than cranberry plants. Tests must be conducted in MA and WI. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN Reg. Nos. MA790001 and WI800081.

[26] Data depicting 2,4-D residues of concern in or on grapes harvested at regular intervals following postemergence directed spray application of the 3.8 lb ae/gal EC MAI formulation (9.5% 2,4-D acid plus 33.36% ae 2,4-D triethylamine salt) in 60 gal of water/A must be submitted. The registrant must propose label amendments establishing a PHI that is reflected in the data requested above. Tests must be conducted in CA (93%) and NY (3%), representing ca. 100 percent of 1985 U.S. grape production.

[27] Data depicting residues of 2,4-D in or on raisins, raisin waste, dry pomace and juice processed from grapes bearing measurable weathered residues must be submitted. If the data indicate a potential for residue concentration any of these commodities, the registrant must propose appropriate food/feed additive regulations.

[28] Data depicting 2,4-D residues of concern in or on strawberries harvested at regular intervals following early spring application of a representative 2,4-D amine salt EC formulation at 1.5 lb ae/A in 20 gal of water/A must be submitted. The registrant must propose label amendments to establish a PHI which is reflected in the data requested above. Tests must be conducted in CA (77%) and FL (14%) representing ca. 91 percent of 1985 U.S. strawberry production.

[29] Data depicting 2,4-D residues in or on almonds, almond hulls, pecans, and English walnuts harvested 60 days after the last of two applications of representative registered 2,4-D formulations at 1.4 lb ae/A in 20 gal/A of water, directed at weeds on the orchard floor must be submitted. Tests must be conducted in CA for almonds and walnuts and in GA (34%), NM (12%), and TX (32%) for pecans representing ca. 100, 100, and 80 percent of 1985 U.S. commercial production for the respective nut crops.

[30] Data depicting 2,4-D residues in or on filberts harvested 45 days following the last of four applications of an EC MAI formulation containing 0.95 lb ae/100 gal water with a spreader-sticker directed spray on suckers must be submitted. Tests must be conducted in OR which accounted for ca. 100% of the 1985 U.S. filbert production.

[31] If the registrant seeks a crop group tolerance, the following additional data are required:

Footnotes (Continued)

°Additional residue data to support the existing tolerances for residues in or on corn (field and fresh), rice, sorghum, and wheat.

[32] The registrants must propose an amendment to all product labels that specifies an appropriate PHI (based on residue data required for wheat) and maximum seasonal application rates and/or number of applications.

[33] Data requested depicting 2,4-D residues in or on wheat grain and in milled products derived from wheat will be translated to barley. Refer to wheat footnotes for details of data requirements.

[34] Data depicting 2,4-D residues of concern in or on corn grain and fresh corn (K+CWHR) harvested at regular intervals after postemergence treatments of each of the following must be submitted: (i) a representative EC formulation of 2,4-D acid at 1.4 lb ae/A applied with ground equipment; (ii) a representative Cr, EC, or SC/L formulation of a dimethylamine salt at 1.5 lb ae/A using ground and aerial equipment in separate tests; (iii) a representative EC formulation of a low volatile ester at 2 lb ae/A using ground and serial equipment in separate tests; and (iv) a representative EC formulation of a high volatile ester at 0.6 lb ae/A applied with ground equipment and with aerial equipment in 1 gal of oil/A. The tests on corn grain must be conducted in IL (17%), IA (19%), NM (8%), NE (11%), and OH(6%) which collectively produced ca. 60 percent of 1985 U.S. corn grain. Tests on fresh corn must be conducted in ID (6%), OR (13%), or WA (12%) and MN (26%) or WI (25%), states that collectively produced ca. 80 percent of 1985 U.S. sweet corn.

[35] Data depicting residues of 2,4-D in or on corn grain and fresh corn (K+CWHR) harvested at regular intervals after layby treatments of each of the following must be submitted: (i) a representative EC or SC/L formulation of a dimethylamine salt at 0.45 lb ae/A using ground and aerial equipment in separate tests; (ii) a representative EC formulation of a low volatile ester at 0.24 lb ae/A using ground equipment; and (iii) a representative EC formulation of a high volatile ester at 1.5 lb ae/A applied with ground equipment. The tests on corn grain must be conducted in IL (17%), IA (19%), MN (8%), NE (11%), and OH (6%) which collectively produced ca. 60 percent of 1985 U.S. corn grain. Tests on fresh corn must be conducted in ID (6%), OR (13%), or WA (12%) and MN (26%) or WI (25%), states that collectively produced ca. 80 percent of 1985 U.S. sweet corn.

[36] Data depicting residues of 2,4-D in or on corn grain and fresh corn (K+CWHR) harvested at regular intervals after postlayby treatments of each of the following must be submitted: (i) a representative EC or SC/L formulation of a dimethylamine salt at 0.71 lb ae/A using ground equipment; (ii) a representative EC formulation of a low volatile ester at 0.48 lb ae/A using ground equipment; and (iii) a representative EC formulation of a high volatile

Footnotes (Continued)

ester at 0.5 lb ae/A applied with ground equipment. The tests on corn grain must be conducted in IL (17%), IA (19%), MN (8%), NE (11%), and OH (6%) which collectively produced ca. 60 percent of 1985 U.S. corn grain. Tests on fresh corn must be conducted in ID (6%), OR (13%), or WA (12%) and MN (26%) or WI (25%), states that collectively produced ca. 80 percent of 1985 U.S. sweet corn.

[37] Data depicting residues of 2,4-D in or on corn grain harvested at regular intervals after preharvest treatments (made after the hard dough or denting stage) of each of the following must be submitted: (i) a representative EC or SC/L formulation of a dimethylamine salt at 1 lb ae/A using ground and aerial equipment in separate tests; (ii) a representative EC formulation of a low volatile ester at 1 lb ae/A using ground and aerial equipment in separate tests; and (iii) a representative EC formulation of a high volatile ester at 0.97 lb ae/A applied with ground equipment and with aerial equipment in 1 gal/water/A must be submitted. The tests on corn grain grain must be conducted in IL (17%), IA (19%), MN (8%), NE (11%), and OH (6%) which collectively produced ca. 60 percent of 1985 U.S. corn grain.

[38] The registrant must propose amendments to all pertinent product labels that specify an appropriate PHI (based on the requested data) and a maximum seasonal application rate that is reflected in the requested data.

[39] Data are required depicting the concentration of 2,4-D residues in starch, crude oil, and refined oil (from wet milling); grits, meal, flour, crude oil, and refined oil (from dry milling) and grain dust processed from corn grain bearing measurable weathered residues. If residues concentrate in any of these commodities, appropriate food/feed additive regulations must be proposed.

[40] Data depicting 2,4-D residues of concern in or on millet grain harvested at regular intervals after postemergence broadcast application of the 3.8 lb ae/gal EC formulation of 2,4-D alkanolamine salt (ethanol and isopropanol series) at 1.43 lb ae/A just before the boot stage, followed in same plot by a preharvest broadcast application of the same formulation at the same rate when grain is in the dough stage must be submitted. The postemergence treatments must be applied, in separate tests, in 5 gal of water/A using ground equipme and 1 gal of water/A using aerial equipment. The registrants must propose label amendments establishing a PHI and specifying a maximum seasonal use rate or maximum number of applications per season. These amendments must be reflected in the data requested above. Tests must be conducted in CO (14%) or NE (11%) and SD (53%) or ND (18%) representing ca. 100 percent of the 1982 U.S. proso millet production.

[41] Data depicting 2,4-D residues of concern in or on millet grain harvested at normal crop maturity following

Footnotes (Continued)

postemergence broadcast application of the 2,4-D DMA salt 4 lb/gal EC formulation at 2 lb ae/A in 5 gal of water/A when the crop is 4 to 6 inches tall must be submitted. Tests must be conducted in ND where this use is permitted by EPA SLN No. ND820015. Alternatively, the registrant may elect to cancel this special local needs use.

[42] Data depicting the potential for concentration of 2,4-D residues of concern in the hulls, meal, and flour processed from grain bearing measurable weathered residues must be submitted. If residues concentrate in any of these milled products, the registrant must propose appropriate food/feed additive regulations.

[43] The registrants must propose an amendment to all product labels that specifies an appropriate PHI (based on residue data required for wheat) and maximum seasonal application rates and/or number of applications.

[44] The required data depicting 2,4-D residues in or on wheat grain and in milled products derived from wheat will be translated to oats. Refer to wheat footnotes for details of data requirements.

[45] Data depicting 2,4-D residues of concern in or on rice grain harvested at regular intervals following the last of multiple, broadcast, directed postemergence applications applied at regular intervals in the minimum amount of water for good weed coverage of the following (in separate tests) must be submitted : (i) a representative EC formulation containing 2,4-D as the acid and n-oleyl-1,3-propylenediamine salt at 0.9 lb ae/A; (ii) the 2.87 lb/gal invert-emulsifiable concentrate (InEC) formulation of the alkylamine (derived from tall oil) salt at 2.9 lb ae/A; (iii) a representative Soluble Concentrate/Solid (SC/S) formulation of the lithium salt at 1.5 lb ae/A (using ground and aerial equipment); and (iv) the 4 lb/gal EC formulation of the propylene glycol butyl ether ester of 2,4-D at 1.25 lb ae/A. The registrants must propose label amendments establishing: (i) appropriate PHIs; (ii) maximum seasonal application rates and/or number of applications and (iii) volume of water to be used as diluent in ground and aerial applications all of which must be reflected in the requested data. Tests must be conducted in AR (40%), LA (15%), and TX (13%), representing ca. 70 percent of 1985 U.S. production of rice.

[46] Data depicting 2,4-D residues of concern in the milled products of rice (bran, hulls, and polished rice) processed from rice bearing measurable weathered residues must be submitted. If the data indicate a potential for concentration of residues in any of these processed commodities, appropriate food/feed additive regulations must be proposed.

[47] The registrants must propose an amendment to all product labels that specifies an appropriate PHI (based

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Footnotes (Continued)

on residue data required for wheat) and maximum seasonal application rates and/or number of applications.

48 Data required depicting residues of 2,4-D in or on wheat grain and in milled fractions derived from wheat will be translated to rye. Refer to wheat footnotes for details of data requirements.

49 Data depicting 2,4-D residues of concern in or on sorghum grain harvested at regular intervals following the last of multiple, postemergence, directed spray applications applied at regular intervals in the minimum amount of diluent for good weed coverage of the following must be submitted: the 79 percent EC acid formulation at 1 lb ae/A; the 2.87 lb/gal InEC alkylamine (derived from tall oil) salt formulation at 2.9 lb ae/A (using ground and aerial equipment in separate tests); a representative EC or SC/L diethanolamine salt formulation at 1 lb ai/A; a representative EC butoxypropyl ester formulation at 0.6 lb ae/A; and a representative EC butyl ester formulation at 0.5 lb ae/A. Applications must be made when sorghum is 8 to 10 inches high. The registrants must propose label amendments establishing (i) appropriate PHIs, (ii) maximum seasonal application rates and/or number of applications, and (ii) allowable ranges of diluent for treatment, all of which must be reflected in the requested data. Tests must be conducted in KS (26%), MO (11%), NE (14%) and TX (22%) which accounted for ca. 70 percent of the 1985 U.S. sorghum production.

50 Data depicting 2,4-D residues of concern in or on sorghum harvested at regular intervals after postemergence broadcast application of a representative SC/S formulation of 2,4-D lithium salt at 0.75 lb ae/A must be submitted. Ground applications must be made in at least 5 gal/A and aerial applications must be made in at least 1 gal/A when the crop is 4 inches high. The registrants must propose a label amendment establishing a PHI and specifying a maximum seasonal use rate or maximum number of applications per season. These amendments must be reflected in the data requested above.

51 Data depicting 2,4-D residues of concern in or on sorghum harvested at regular intervals following application of the 5.64 lb/gal EC formulation of 2,4-D butyl ester must be submitted. The registrant must propose label amendments specifying the rates of application, a maximum seasonal use rate or maximum number of applications per season, and establishing a PHI. These amendments must be reflected in the data requested above. Tests must be conducted in KS. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN No. KS820008.

52 Data depicting the potential for concentration of 2,4-D residues of concern in flour and starch processed

Footnotes (Continued)

from grain bearing measurable weathered residues must be submitted. If residues concentrate in any of these milled products, the registrant must propose appropriate food additive regulations.

53 Data depicting 2,4-D residues of concern in or on wheat grain harvested at regular intervals after postemergence broadcast application of the following must be submitted: (i) a representative EC MAI formulation containing 2,4-D acid plus n-oleyl-1,3-propylenediamine salt at 1.42 lb ae/A in 5 gal water/A using ground equipment, and in a separate test, using aerial equipment in the minimum amount of diluent for adequate coverage; (ii) a representative (SC/S) formulation of 2,4-D lithium salt at 0.5 lb ae/A in 20 gal water/A using ground equipment only; (iii) the 2.87 lb ae/gal InEC formulation of 2,4-D alkylamine salt (derived from tall oil) at 2.9 lb ae/A using ground and aerial equipment, in separate tests, in the minimum amount of diluent for adequate coverage; (iv) a representative EC formulation of 2,4-D butoxyethyl ester at 0.95 lb ae/A in 5 gal water/A and in 2 gal oil/A using ground and aerial equipment respectively, in separate tests; (v) a representative EC formulation of 2,4-D butyl ester at 1.4 lb ae/A in 5 gal water/A using ground equipment and in 1 gal water/A using aerial equipment in separate tests; and (vi) a representative EC or SC/L formulation of 2,4-D dimethylamine salt at 1.44 lb ae/A in 10 gal of water/A using ground equipment and in a separate test in 3 gal water/A using aerial equipment. The registrant must amend all 2,4-D product labels specifying appropriate PHIs, minimum amounts of diluent, and a maximum seasonal use rate or maximum number of applications per season. These amendments must be reflected in the data requested above. Tests must be conducted in KS (18%), or CO (6%), MN (6%), ND (13%), or SD (5%), TX (8%) or OK (7%), and WA (5%) or MT (2%) since these states collectively accounted for ca. 70 percent of 1985 U.S. total wheat-growing regions in the U.S.

54 Data depicting 2,4-D residues of concern in or on wheat grain harvested at regular intervals following preharvest broadcast applications of the following must be submitted: (i) a representative EC MAI formulation containing 2,4-D acid plus n-oleyl-1,3-propylenediamine salt at 1.42 lb ae/A in 5 gal water/A using ground equipment, in a separate test and using aerial equipment in the minimum amount of diluent for adequate coverage; (ii) the 3.8 lb ae/gal SC/L MAI formulation (16.3% diethanolamine salt plus 33.2% dimethylamine salt) at 1.5 lb ae/A using ground and aerial equipment in separate tests in the minimum amount of diluent for adequate coverage; (iii) a representative EC formulation of 2,4-D propylene glycol butyl ether ester at 1 lb ae/A using ground and aerial equipment, in separate tests, in the minimum amount of diluent for adequate coverage; and (iv) the 6 lb ae/gal EC MAI formulation (38.8% butyl ester plus 36.8% isopropyl ester) at 1.12 lb ae/A in 1 gal oil/A. The registrants must amend all 2,4-D product labels specifying appropriate PHIs, minimum amount of diluent, and a maximum seasonal use rate or maximum number of applications per season. These amendments must be reflected in the data requested above.

Footnotes (Continued)

55 Data depicting 2,4-D residues of concern in or on wheat grain harvested at regular intervals following postemergence broadcast applications of the 3.8 lb ae/gal SC/L MAI formulation containing 2,4-D acid plus 2,4-D DMA salt at 1 lb ae/A must be submitted. Applications must be made in 1 and 0.5 gal water/A using ULV ground and aerial equipment, respectively, in separate tests. Tests must be conducted in ID, KS, MT, NE, ND, OR, SD, UT, and WA states in which this use is permitted. The registrant must amend all product labels specifying an appropriate PHI and a maximum number of applications per season or a maximum seasonal application rate. Alternatively, the registrants may cancel this use permitted under EPA SLN Nos. ID820032, KS830014, MT820011, NE830006, ND820013, OR820056, SD830004, UT830002, and WA820057.

56 Data depicting 2,4-D residues of concern in bran, middlings, shorts, and grain dusts processed from wheat grain bearing measurable weathered residues must be submitted. The established food/feed additive regulations for residues of 2,4-D in milled products (excluding flour) will be reassessed following evaluation of these data.

57 The registrant must propose food additive regulations for residues of 2,4-D in flour. 2,4-D residues may concentrate up to 2x in flour processed from treated wheat grain. The establishment of any regulation is dependent upon toxicological considerations.

58 Available data are insufficient to determine the appropriateness of a crop group tolerance. Additional data are required to support the established tolerances for residues in or on corn, wheat, and one additional member of the cereal grains group.

59 Data required for wheat forage will be translated to barley forage. Refer to wheat forage footnote for details of data requirements. The registrant must propose amendments to all product labels that specify an appropriate PHI (based on residue data required for wheat) and maximum seasonal application rates and/or number of applications.

60 Data depicting 2,4-D residues of concern in or on corn forage and fodder harvested at regular intervals after postemergence treatments of each of the following must be submitted: (i) a representative EC formulation of 2,4-D acid at 1.4 lb ae/A applied with ground equipment; (ii) a representative Cr, EC, or SC/L formulation of a dimethylamine salt at 1.5 lb ae/A using ground and aerial equipment in separate tests; (iii) a representative EC formulation of a low volatile ester at 2 lb ae/A using ground and aerial equipment in separate tests; and (iv) a representative EC formulation of a high volatile ester at 0.6 lb ae/A applied with ground equipment and with aerial equipment in 1 gal of oil/A. The tests on corn grain must be conducted in IL (17%), IA (19%), MN (8%), NE (11%), and OH(6%) which collectively produced ca. 60 percent of 1985 U.S. corn grain. Tests on fresh corn must be conducted in ID (6%), OR (13%), or WA (12%) and MN (26%) or WI (25%), states that collectively produced ca. 80

Footnotes (Continued)

percent of 1985 U.S. sweet corn.

[61] Data depicting 2,4-D residues of concern in or on corn forage and fodder harvested at regular intervals after layby treatments of each of the following must be submitted: (i) a representative EC or SC/L formulation of a dimethylamine salt at 0.45 lb ae/A using ground and aerial equipment in separate tests; (ii) a representative EC formulation of a low volatile ester at 0.24 lb ae/A using ground equipment; and (iii) a representative EC formulation of a high volatile ester at 1.5 lb ae/A applied with ground equipment. The tests on corn grain must be conducted in IL (17%), IA (19%), MN (8%), NE (11%), and OH (6%) which collectively produced ca. 60 percent of 1985 U.S. corn grain. Tests on fresh corn must be conducted in ID (6%), OR (13%), or WA (12%) and MN (26%) or WI (25%), states that collectively produced ca. 80 percent of 1985 U.S. sweet corn.

[62] Data depicting 2,4-D residues of concern in or on corn forage and fodder harvested at regular intervals after postlayby treatments of each of the following must be submitted: (i) a representative EC or SC/L formulation of a dimethylamine salt at 0.71 lb ae/A using ground equipment; (ii) a representative EC formulation of a low volatile ester at 0.48 lb ae/A using ground equipment; and (iii) a representative EC formulation of a high volatile ester at 0.5 lb ae/A applied with ground equipment. The tests on corn grain must be conducted in IL (17%), IA (19%), MN (8%), NE (11%), and OH (6%) which collectively produced ca. 60 percent of 1985 U.S. corn grain. Tests on fresh corn must be conducted in ID (6%), OR (13%), or WA (12%) and MN (26%) or WI (25%), states that collectively produced ca. 80 percent of 1985 U.S. sweet corn.

[63] Data depicting 2,4-D residues of concern in or on corn forage and fodder harvested at regular intervals after preharvest treatments (made after the hard dough or denting stage) of each of the following must be submitted: (i) a representative EC or SC/L formulation of a dimethylamine salt at 1 lb ae/A using ground and aerial equipment in separate tests; (ii) a representative EC formulation of a low volatile ester at 1 lb ae/A using ground and aerial equipment in separate tests; and (iii) a representative EC formulation of a high volatile ester at 0.97 lb ae/A applied with ground equipment and with aerial equipment in 1 gal/water/A. The tests on grain must be conducted (17%), IA (19%), NM (8%), NE (11%), and OH (6%) which collectively produced ca. 60 percent of 1985 U.S. corn grain.

[64] The registrant must propose label amendments to all products that specify an appropriate PHI (based on the required data) and a maximum seasonal application rate.

[65] Since oat hay is a raw agricultural commodity, the registrant must propose tolerances and submit appropriate

Footnotes (Continued)

supporting residue data. Alternatively, the registrant may amend all pertinent labels to prohibit the feeding of oat hay to livestock.

[66] Data required for wheat forage will be translated to oat forage. Refer to wheat forage footnotes for details of data requirements.

[67] Data depicting 2,4-D residues of concern in or on rice straw harvested at regular intervals following the last of multiple, broadcast, directed, postemergence applications applied at regular intervals in the minimum amount of water for good weed coverage of the following (in separate tests) must be submitted: (i) a representative EC formulation containing 2,4-D as the acid and n-oleyl-1,3-propylenediamine salt at 0.9 lb ae/A; (ii) the 2.87 lb/gal InEC formulation of the alkylamine (derived from tall oil) salt at 2.9 lb ae/A; (iii) a representative SC/S formulation of the lithium salt at 1.5 lb ae/A (using ground aerial equipment); and (iv) the 4 lb/gal EC formulation of the propylene glycol butyl ether ester at 1.25 lb ae/A. The registrants must propose label amendments establishing (i) appropriate PHIs; (ii) maximum seasonal application rates and/or number of applications; and (iii) volume of water to be used as diluent in ground and aerial applications, all of which must be reflected in the requested data. Tests must be conducted in AR (40%), LA (15%), and TX (13%), representing ca. 70 percent of 1985 U.S. production of rice.

[68] Data required for wheat forage will be translated to rye forage. Refer to wheat forage footnotes for details of da requirements.

[69] Data depicting 2,4-D residues of concern in or on sorghum forage and sorghum fodder harvested at regular intervals following the last of multiple postemergence directed spray applications applied at regular intervals in the minimum amount of diluent for good weed coverage of the following must be submitted: the 79 percent EC formulation containing 2,4-D as the acid at 1 lb ae/A; the 2.87 lb/gal InEC formulation of 2,4-D alkylamine (derived from tall oil) salt at 2.9 lb ae/A; a representative EC or SC/L formulation of 2,4-D diethanolamine salt at 1 lb ae/A (using ground and aerial equipment in separate tests); a representative EC formulation of 2,4-D butoxypropyl ester at 0.6 lb ae/A; and a representative EC formulation of 2,4-D butyl ester at 0.5 lb ae/A (in 10 gal/A using ground equipment and 3 gal/water/A using aerial equipment, in separate tests). Applications must be made when sorghum is 8 to 10 inches high. The registrants must propose label amendments establishing: (i) appropriate PHIs, (ii) maximum seasonal application rates and/or number of applications, and (iii) allowable ranges of diluent for treatment, all of which must be reflected in the requested data. Tests must be conducted

Footnotes (Continued)

in KS (26%), MO (11%), NE (14%) and TX (22%) which accounted for ca. 70 percent of the 1985 U.S. sorghum production.

70 Data depicting 2,4-D residues of concern in or on sorghum forage and fodder harvested at regular intervals after postemergence broadcast application of a representative SC/S formulation of 2,4-D lithium salt at 0.75 lb ae/A must be submitted. Ground applications must be made in at least 5 gal/water/A and aerial applications must be made in at least 1 gal/water/A when the crop is 4 inches high. The registrants must propose a label amendment establishing a PHI and specifying a maximum seasonal use rate or maximum number of applications per season. These amendments must be reflected in the data requested above.

71 Data depicting 2,4-D residues of concern in or on sorghum forage and fodder harvested at regular intervals following application of the 5.64 lb/gal EC formulation of 2,4-D butyl ester must be submitted. The registrant must propose label amendments specifying the rates of application, a maximum seasonal use rate or maximum number of applications per season, and establishing a PHI. These amendments must be reflected in the data requested above. Tests must be conducted in KS. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN No. KS820008.

72 Data depicting 2,4-D residues of concern in or on wheat forage harvested 14 days after postemergence broadcast application of the following must be submitted. (i) a representative EC MAI formulation containing 2,4-D acid plus n-oleyl-1,3-propylenediamine salt at 1.42 lb ae/A in 5 gal water/A using ground equipment, and in a separate test, using aerial equipment in the minimum amount of diluent for adequate coverage; (ii) a representative SC/S formulation of 2,4-D lithium salt at 0.5 lb ae/A in 20 gal water/A using ground equipment only; (ii) the 2.87 lb ae/gal InEC formulation of 2,4-D alkylamine salt (derived from tall oil) at 2.9 lb ae/A using ground and aerial equipment, in separate tests, in the minimum amount of diluent for adequate coverage; (iv) a representative EC formulation of 2,4-D butoxyethyl ester at 0.95 lb ae/A in 5 gal water/A and in 2 gal oil/A using ground and aerial equipment respectively, in separate tests; (v) a representative EC formulation of 2,4-D butyl ester at 1.4 lb ae/A in 5 gal water/A using ground equipment and in 1 gal water/A using aerial equipment in separate tests; and (vi) a representative EC or SC/L formulation of 2,4-D dimethylamine salt at 1.44 lb ae/A in 10 gal of water/A using ground equipment and in a separate test in 3 gal water/A using aerial equipment. The registrants must amend all 2,4-D product labels specifying appropriate PHIs, minimum amount of diluent, and a maximum seasonal use rate or maximum number of applications per season. These amendments must be reflected in the data requested above. Tests must be conducted in KS (18%), or CO (6%), MN (6%), ND (13%), or SD (5%), TX (8%) or OK (7%), and WA (5%) or MT (2%) since these states collectively accounted for ca. 70 percent of 1985 U.S. total wheat-growing regions in the U.S.

Footnotes (Continued)

[73] Data depicting 2,4-D residues of concern in or on wheat forage harvested 14 days following preharvest broadcast applications of the following must be submitted: (i) a representative EC MAI formulation containing 2,4-D acid plus n-oleyl-1,3-propylenediamine salt at 1.42 lb ae/A in 5 gal water/A using ground equipment, and in a separate test, using aerial equipment in the minimum amount of diluent for adequate coverage; (ii) the 3.8 lb ae/gal SC/L MAI formulation (16.3% diethanolamine salt plus 33.2% dimethylamine salt) at 1.5 lb ae/A using ground and aerial equipment in separate tests in the minimum amount of diluent for adequate coverage; (iii) a representative EC formulation of 2,4-D propylene glycol butyl ether ester at 1 lb ae/A using ground and aerial equipment, in separate tests, in the minimum amount of diluent for adequate coverage; and (iv) the 6 lb ai/gal EC MAI formulation (38.8% butyl ester plus 36.8% isopropyl ester) at 1.12 lb ae/A in 1 gal oil/A. The registrants must amend all 2,4-D product labels specifying appropriate PHIs, minimum amount of diluent, and a maximum seasonal use rate or maximum number of applications per season. These amendments must be reflected in the data requested above.

[74] Data depicting 2,4-D residues of concern in or on wheat forage harvested at regular intervals following postemergence broadcast applications of the 3.8 lb ae/gal SC/L MAI formulation containing 2,4-D acid plus 2,4-D DMA salt at 1 lb ae/A must be submitted. Applications must be made in 1 and 0.5 gal water/A using ULV ground and aerial equipment respectively, in separate tests. Tests must be conducted in ID, KS, MT, NE, ND, OR, SD, UT, and WA, states in which this use is permitted. The registrant must amend all product labels specifying an appropriate PHI and a maximum number of applications per season or a maximum seasonal application rate. Alternatively, the registrants may cancel this use permitted under EPA SLN Nos. ID820032, KS830014, MT820011, NE830006, ND820013, OR820056, SD830004, UT830002, and WA820057.

[75] Data depicting 2,4-D residues of concern in or on rangeland and pasture grasses (7 day PGI), and grass hay harvested 30 days following application in the minimum amount of water for good weed coverage of the following (in separate tests) must be submitted. (i) a representative EC formulation containing 2,4-D acid at 2.8 lb ae/A by ground equipment; (ii) a representative SC/S formulation containing an inorganic salt at 3.0 lb ae/A by ground equipment; (iii) a representative EC formulation containing an amine salt and 2,4-D acid at 5.7 lb ae/A by ground or aerial equipment; (v) a representative EC or SC/L formulation containing a low volatile ester at 3.87 lb ae/A in oil by aerial equipment; (vii) a representative EC formulation containing a high volatile ester at 13.1 lb ae/A by dilute (up to 400 gal/A) ground equipment; and, (viii) a representative EC formulation containing a high volatile ester at 3.0 lb ae/A in oil by ground or aerial equipment. The registrant must include the 7-day PGI and the 30-day PHI for grass hay on all labeling. In addition, the registrant must lower the existing 7-day PSI to 3 days on all labeling. Tests must be conducted in AR (3%), KS (4%), KY (6%), MO (11%), NY (5%), OK (4%), PA (4%), TN

Footnotes (Continued)

(4%), TX (13%), and VA (3%) which produced ca. 60 percent of the total 1982 domestic hay crop (other than alfalfa and small grains) and which may represent pasture grasses as well. For rangeland grasses, tests must be conducted in KS (8%), MT (6%), NE (17%), ND (10%), OK (5%), SD (12%), and WY (5%) which produced ca. 63 percent of the total wild hay.

76 Data depicting 2,4-D residues of concern in or on rangeland or pastureland grass 7 days (30 days for grass hay) following application of a RTU formulation containing a water-soluble amine salt at 3.0 lb ae/A applied undiluted by aerial equipment must be submitted. Tests must be conducted in WA. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN WA790065.

77 Data depicting 2,4-D residues of concern in or on rangeland or pastureland grass 7 days (30 days for grass hay) following application of an 18.8% G formulation containing an isooctyl ester at 1.88 lb ae/A by spreader must be submitted. Tests must be conducted in MT. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN MT850005.

78 The registrant must propose a maximum seasonal use rate or number of treatments per season and the allowable ranges of diluent for treatment all of which must be reflected in the requested data.

79 Data depicting 2,4-D residues of concern in or on asparagus following two 2 lb ae/A applications at 30-day intervals of the 79 percent EC acid, the 80.5 percent SC/L sodium salt, and the 3.8 lb ae/gal EC alkanolamine salt (ethanol and isopropanol series) formulations (each formulation must be applied in a separate test using both ground and aerial equipment with 60 and 12 gal/A of water, respectively) must be submitted. Applications must be made in April and May and if asparagus spears are visible must be delayed until after cutting. The registrant must propose a minimum postharvest interval. Tests must be conducted in CA (39%) or WA (31%) and MI (20%) which collectively accounted for ca. 90 percent of the U.S. asparagus acreage.

80 Data depicting 2,4-D residues of concern in or on pistachios harvested 60 days following the last of two postemergence directed spray applications of the 3.8 lb ae/gal EC MAI formulation (16.3% 2,4-D diethanolamine salt plus 33.2% 2,4-D DMA salt) at 1.4 lbs ae/A/application (in 20 gal water/A) must be submitted. Tests must be conducted in CA which accounted for ca. 100 percent of the 1982 U.S. pistachio production.

81 Data depicting residues of 2,4-D in or on sugarcane and sugarcane forage harvested at regular intervals following each of these treatment schedules must be submitted: (i) broadcast applications of a representative MAI

Footnotes (Continued)

formulation containing 2,4-D acid and the N-oleyl-1,3-propylenediamine salt of 2,4-D at 1.8 lb ae/A made postemergence at layby; (ii) preemergence and postemergence broadcast or band applications of a representative EC or SC/L formulation of the dimethylamine salt of 2,4-D at 2 lb ae/A; and (iii) broadcast applications of a representative EC formulation of the 2-butoxyethyl ester or the isooctyl ester form of 2,4-D at 1.9 lb/A made postemergence through layby. The required data must reflect the use of ground and aerial equipment in separate tests. The registrant must amend all pertinent labels to specify a PHI and a maximum number of applications per season. Tests must be conducted in FL (47%), HI (29%), and LA (20%), states that collectively accounted for 96 percent of 1985 U.S. production of sugarcane. The established food/feed additive regulations for residues in sugarcane molasses and bagasse will be reassessed following evaluation of these data.

[82] Upon receipt of the required plant metabolism, residue data for feed items, and validation of analytical methods, the need for and nature of tolerances for 2,4-D residues of concern in livestock and poultry will be assessed.

[83] A metabolism study must be submitted in which fish are exposed (for at least 3 days) to water containing [^{14}C]2,4-D at a concentration sufficiently high to permit complete quantification and characterization of ^{14}C-residues in edible tissues (flesh and skin).

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.340 - Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	ACID - TGAI	Yes	00101605, 00101591	No	
	AMINE - TGAI	No		Yes [2]	9 Months
	ESTER - TGAI	Partially	00101595, 00101601 00138284, 40629801	Yes [3]	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	ACID - TGAI	Yes	00101596	No	
	AMINE - TGAI	No		Yes[2]	9 Months
	ESTER - TGAI	Partially	00101592, 00101600 00138284, 40629802	Yes[3]	9 Months
81-3 - Acute Inhalation Toxicity - Rat	ACID - TGAI	Yes	00161660	No	
	AMINE - TGAI	No		Yes[2]	9 Months
	ESTER - TGAI	Partially	40352701, 40629803	Yes[4]	9 Months
81-4 - Eye Irritation - Rabbit	ACID - TGAI	No		Yes	9 Months
	AMINE - TGAI	No		Yes[2]	9 Months
	ESTER - TGAI	Partially	40352702, 40629804	Yes[4]	9 Months
81-5 - Dermal Irritation - Rabbit	ACID - TGAI	No		Yes	9 Months
	AMINE - TGAI	No		Yes[2]	9 Months
	ESTER - TGAI	Partially	40352703, 40629805	Yes[4]	9 Months
81-6 Dermal Sensitization -Guinea Pig	ACID - TGAI	Yes	00161659	No	
	AMINE - TGAI	No		Yes[2]	9 Months
	ESTER - TGAI	Partially	00156564, 00156637 40352704, 40629806	Yes[4]	9 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]
§158.340 - Toxicology - Continued					
81-7 - Acute Delayed Neurotoxicity - Hen	ACID - TGAI	No		No[5]	
	AMINE - TGAI	No		No[5]	
	ESTER - TGAI	No		No[5]	
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding: - Rodent, and	ACID - TGAI	No		No[6]	
	AMINE - TGAI	No		Yes	15 Months
	ESTER - TGAI	No		Yes	15 Months
- Non-rodent (Dog)	ACID - TGAI	No		No[7]	
	AMINE - TGAI	No		Yes	18 Months
	ESTER - TGAI	No		Yes	18 Months
82-2 - 21-Day Dermal	ACID - TGAI	No		Yes	12 Months
	AMINE - TGAI	No		Yes	12 Months
	ESTER - TGAI	No		Yes	12 Months
82-3 - 90-Day Dermal	ACID - TGAI	No		No[8]	
	AMINE - TGAI	No		No[8]	
	ESTER - TGAI	No		No[8]	
82-4 - 90-Day Inhalation:	ACID - TGAI	No		No[8]	
	AMINE - TGAI	No		No[8]	
	ESTER - TGAI	No		No[8]	
82-5 - 90-Day Neurotoxicity:	ACID - TGAI	No		No[9]	
	AMINE - TGAI	No		No[9]	
	ESTER - TGAI	No		No[9]	

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission^{1}
CHRONIC TESTING					
83-1 - Chronic Toxicity - 2 species:					
- Rodent, and	ACID - TGAI	Yes	00160876	No	
	AMINE - TGAI	No		Reserved^{10,11}	
	ESTER - TGAI	No		Reserved^{10,11}	
- Non-rodent (Dog)	ACID - TGAI	No		Yes^{11}	50 Months
	AMINE - TGAI	No		Reserved^{10,11}	
	ESTER - TGAI	No		Reserved^{10,11}	
83-2 - Oncogenicity - 2 species:					
- Rat	ACID - TGAI	Partially	00160876	Reserved^{12}	
	AMINE - TGAI	No		Reserved^{10}	
	ESTER - TGAI	No		Reserved^{10}	
- Mouse	ACID - TGAI	Partially	40061801	Reserved^{12}	
	AMINE - TGAI	No		Reserved^{10}	
	ESTER - TGAI	No		Reserved^{10}	
83-3 - Teratogenicity - 2 species:					
- Rat	ACID - TGAI	Yes	00130407, 00130707	No	
	AMINE - TGAI	No		Yes	15 Months
	ESTER - TGAI	No		Yes	15 Months
- Rabbit	ACID - TGAI	No		Yes	15 Months
	AMINE - TGAI	No		Yes	15 Months
	ESTER - TGAI	No		Yes	15 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]
§158.340 - Toxicology - Continued					
83-4 - Reproduction - Rat 2-generation	ACID - TGAI	Yes	00150557	Reserved[13]	
	AMINE - TGAI	No		Reserved[13]	
	ESTER - TGAI	No		Reserved[13]	
MUTAGENICITY TESTING					
84-2 - Gene Mutation	ACID - TGAI	No		Yes	9 Months
	AMINE - TGAI	No		Yes	9 Months
	ESTER - TGAI	No		Yes	9 Months
84-2 - Structural Chromosomal Aberration	ACID - TGAI	No		Yes	12 Months
	AMINE - TGAI	No		Yes	12 Months
	ESTER - TGAI	No		Yes	12 Months
84-2 - Other Mechanisms of Mutagenicity	ACID - TGAI	No		Yes	12 Months
	AMINE - TGAI	No		Yes	12 Months
	ESTER - TGAI	No		Yes	12 Months
SPECIAL TESTING					
85-1 - General Metabolism	ACID - TGAI	No		Yes	24 Months
	AMINE - TGAI	No		Yes	24 Months
	ESTER - TGAI	No		Yes	24 Months
81-X - Neurotoxicity (dermal)	ACID - TGAI	No		Yes[14]	12 Months
	AMINE - TGAI	No		Yes[14]	12 Months
	ESTER - TGAI	No		Yes[14]	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

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§158.340 Toxicology Footnotes

1 Data must be submitted within the indicated timeframes, which begin on receipt of the Guidance Document.

2 Data must be submitted for each amine derivative of 2,4-D. The data submitted on 2,4-D Triethanolamine Salt could not be reviewed as the compound tested was not sufficiently identified (MRIDs 40515701, 40515702, 40515703, 40515704, 40515705, 40515706).

3 The Agency has acceptable data on 2,4-D butoxyethyl ester, 2,4-D isooctyl ester, 2,4-D isobutyl ester and 2,4-D isopropyl ester. Data must be submitted for each remaining ester derivative of 2,4-D.

4 The Agency has acceptable data on 2,4-D butoxyethyl ester and 2,4-D isopropyl ester. Data must be submitted for each remaining ester derivative of 2,4-D.

5 This test is required only for compounds which are organophosphate inhibitors of cholinesterase, or related to such inhibitors or metabolites of such inhibitors. 2,4-D acid and its salts, amines and esters are not organophosphates, therefore, a study is not required.

6 This requirement is waived for 2,4-D acid based on the submission of an acceptable chronic feeding study in the rat.

7 This requirement is waived for 2,4-D acid based on the requirement of a chronic feeding study in the nonrodent.

8 This study is not required for the registered use patterns.

9 Since an acute neurotoxicity study is not required for these compounds, this study is not required. If evidence of neurotoxicity in a mammalian species is observed a study will be required in that species.

10 Upon receipt and evaluation of the data required for each amine and ester, additional chronic toxicology and residue data may be required. Upon determination by the Agency that these studies are required, registrants will be notified and data will be due 50 months from date of notification.

§158.340 Toxicology Footnotes (Continued)

11 Registrants who conduct chronic feeding studies must inform the Agency in writing of the dosage levels planned and their reasons for believing that the highest dose approaches or equals the Maximum Tolerated Dose observed in subchronic or range finding studies, and must also consult with the Agency to determine that the appropriate dosage levels are being used in the chronic feeding and/or oncogenicity studies. If registrants do not consult with the Agency and EPA determines that the dosages used were too low to assess long term toxic effects, the Agency will determine that the submitted studies do not satisfy applicable requirements and may issue a Notice of Intent to Suspend the product(s).

12 Reserved pending independent evaluation of all kidney slides from the relevant chronic and subchronic studies.

13 Upon receipt and evaluation of the data required for each amine and ester, additional chronic toxicology and residue data may be required. Upon determination by the Agency that these studies are required, registrants will be notified and data will be due 39 months from date of notification.

14 A protocol must be submitted and approved by the Agency prior to submission of this study. For such studies the following must be addressed.

°An experimental animal species must be chosen that has been shown to respond to a "chemical known to produce sensory paresthesiaes like those seen most often in the case reports".

°Parameters observed must have been shown to detect the effects, in experimental animals, of a known neurotoxin having this type of effect in man.

°The dose tested must be a single large dermal dose, in the order of an LD_{10}, which produces obvious signs of toxicity. The dose may be applied to the skin of the back and the test animals observed for at least 30 days after dosing.

°The compound tested should be 2,4-D acid or Na salt and each of the organic amine salts and organic esters.

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS[1]

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]
§158.290 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,D,G	No		Yes	9 Months
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B,C,D,G	No		Yes	9 Months
161-3 - On soil	TGAI or PAIRA	A,G	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A	No		Yes	9 Months
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,G	Partially	00116625	Yes[3]	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C,D,G	No		Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	C,D	No		Yes	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,D,G	Partially	00057313 00112937	Yes[4]	12 Months
163-2 - Volatility (Lab)	TEP	A	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No		Yes	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS[1]

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]
§158.290 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD						
164-1 - Soil	TEP	A,B	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	C,D,G	No		Yes	27 Months
164-3 - Forestry	TEP	G	No		Yes	27 Months
164-4 - Combination and Tank Mixes	TEP	-	No		No[5]	--
164-5 - Soil, Long-term	TEP	A,C	No		Reserved[6]	
ACCUMULATION STUDIES						
165-1 - Rotational Crops (Confined)	PAIRA	A,C	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A,C	No		Reserved[7]	
165-3 - Irrigated Crops	TEP	C,D	No		Yes	39 Months
165-4 - In Fish	TGAI or PAIRA	A,B,C,D,G	Partially	00110675	Yes[8]	12 Months
165-5 - In Aquatic Non-Target Organisms	TEP	D,G	Partially	00110675	Yes[8]	12 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS[1]

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§158.290 Environmental Fate Footnotes

[1] Requirements of this data table apply to all products (as prescribed by registered use) containing the 2,4-Dichlorophenoxyacetic acid or inorganic cations and each ester and amine derivative of 2,4-D. Special emphasis on the ester and amine derivatives should be given to the fate of the ester or amine moieties in the environment.

[2] Data must be submitted within the indicated timeframes, which begin upon receipt of the Guidance Document.

[3] The Agency has acceptable data for 2,4-D acid and its inorganic salts. Data are required for each ester and amine derivative of 2,4-D.

[4] This data requirement is partially fulfilled for 2,4-D acid and inorganic salts. Addditional mobility data is required on unaged 2,4-D in a sediment and on aged 2,4-D in soil. This data requirement must be fulfilled for each ester and amine derivative of 2,4-D.

[5] Tank mix data requirements are not being imposed by this standard.

[6] Soil long term study with 2,4-D acid and 2,4-D ester and amine derivatives is reserved pending results of acceptable field dissipation studies with 2,4-D and with each ester and amine derivative of 2,4-D.

[7] The rotational crop field study is reserved pending the results of an acceptable confined rotational crop study on 2,4-D or its inorganic salts and on each ester and amine derivative of 2,4-D.

[8] Data will not be required if acceptable octanol/water partition coefficient data indicating low potential for bioaccumulation are submitted. Octanol/water partition coefficient data are required for 2,4-D acids or its inorganic salts and for each ester and amine derivative.

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS[1]

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]
§158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No		No[3]	
132-1 - Soil Dissipation	TEP	A	No		No[3]	
133-3 - Dermal Exposure	TEP	A,B	No		No[3]	
133-4 - Inhalation Exposure	TEP	A,B	No		No[3]	
§158.440 Spray Drift						
201-1 - Droplet Size	TEP	A,B,C,D,G	No		Yes[4]	12 Months
201-1 - Drift Field	TEP	A,B,C,D,G	No		Yes[4]	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS[1]

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§158.390 Reentry Protection Footnotes

[1] Requirements of this data table apply to all products (as prescribed by registered use) containing the 2,4-D acid and each amine and ester derivative of 2,4-D.

[2] Data must be submitted within the indicated timeframes, which begin upon receipt of the Guidance Document.

[3] Reentry data requirements are not being imposed under this standard.

[4] The droplet spectrum study is to be performed to reflect the nozzle and other equipment types to be used in the application of 2,4-D and each amine and ester derivative of 2,4-D to crops, non-crops and forestry products. The spray drift field evaluation is to be performed to reflect the application, equipment, use pattern, and typical locations of use, which includes different weather factors, in the application of 2,4-D for these uses.

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.490 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,C,D,G	Partially	00160000	Yes[2]	9 Months
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird, and	TGAI	A,B,C,D,G	No		Yes	9 Months
- Waterfowl	TGAI	A,B,C,D,G	No		Yes	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A,B,G	No		No[3]	
71-4 - Avian Reproduction	TGAI	A,B,G	No		Reserved[4]	
71-5 - Simulated and Actual Field Testing						
- Mammals, and	TEP	A,B,G	No		Reserved[5]	
- Birds	TEP	A,B,G	No		Reserved[5]	

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.490 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity						
Warmwater	TGAI	A,B,C,D,G	Partially	40098001	Yes[6]	9 Months
Coldwater	TGAI	A,B,C,D,G	Partially	40098001	Yes[6,7]	9 Months
Warmwater	TEP	A,B,C,D	Partially	00050678, 00050681 00050715, 00054025 00054045, 40098001, 40600203	Yes[8]	9 Months
Coldwater	TEP	A,B,C,D	Partially	00050669, 00050712 00050713, 00053986 00050674, 00053996	Yes[9]	9 Months
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,C,D,G	Partially	00102908, 40098001	Yes[10]	9 Months
	TEP	A,B,C,D	Partially	00054025, 40098001	Yes[11]	9 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	A,B,C,D,G	Partially	40228401	Yes[12]	12 Months
72-4 - Fish Early Life Stage, and Aquatic Invertebrate Life-Cycle	TGAI	A,B,C,D	No		Yes[13]	12 Months
72-5 - Fish - Life-Cycle	TGAI	A,B,C,D	No		Reserved14	

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.490 Wildlife and Aquatic Organisms - Continued						
72-6 - Aquatic Organism Accumulation	TGAI	A,B,C,D	No		Yes[15]	12 Months
72-7 - Simulated and Actual Field Testing - Aquatic Organisms	TEP	A,B,C,D	No		Reserved[4]	

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[1] Data must be submitted within the indicated timeframes, which begin on receipt of the Guidance Document.

[2] The Agency has acceptable data on 2,4-D acid. Data must be submitted on salts, amines and esters.

[3] Not currently a requirement.

[4] Reserved pending receipt and review of all environmental fate data.

[5] Reserved pending receipt and review of all environmental fate data. This study is not required for 2,4-D acid, 2,4-D Lithium Salt, 2,4-D Sodium Salt, and 2,4-D Alkanolamine Salt because of the use.

[6] The Agency has acceptable data on 2,4-D Propylene Glycol Butyl Ether Ester, and 2,4-D acid. Data must be submitted on all other salts, amines and esters.

[7] The Agency has acceptable data on 2,4-D Propylene Glycol Butyl Ether Ester and 2,4-D acid. Data must be submitted on all other salts, amines and esters. Testing is required for 2,4-D Butoxypropyl Ester products having 67.2 percent acid equivalent.

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§158.490 Footnotes (Continued)

8 The Agency has acceptable data on 2,4-D Butoxyethanol ester, 2,4-D Propylene Glycol Butyl Ether Ester, 2,4-D Lithium Salt, 2,4-D Alkanolamine Salt, and 2,4-D Alkyl Amine (C12/C14) Salt. Data must be submitted for all other salts amines, and esters. Testing is required for 2,4-D acid products having the following percent acid equivalent: 79.0, and MAI 8.5; 2,4-D Sodium Salt products having 17.5 and MAI 0.36 acid equivalent; and other 2,4-D derivatives having aquatic uses.

9 The Agency has acceptable data on 2,4-D Butoxyethanol Ester, 2,4-D Butoxypropyl Ester, 2,4-D Sodium Salt, 2,4-D alkanolamine Salt, and 2,4-D Alkyl Amine (C12/C14) Salt. Testing is required for products having the following percent acid equivalent: 2,4-D Propylene Glycol Butyl Ether Ester products 72.8, 41.0, 68.6; 2,4-D Acid 9.5, 10.3, 13.8, 15.9, 21.6, and 22.8; and 2,4-D Lithium Salt 85.0 and 95.0. Data must be submitted on all other 2,4-D derivatives with aquatic uses.

10 The Agency has acceptable data on 2,4-D Propylene Glycol Butyl Ether Ester. Data must be submitted on 2,4-D acid and all other salts, amines and esters.

11 The Agency has acceptable data on 2,4-D Butoxyethanol Ester. Testing is required for products having the following percent acid equivalent: 2,4-D acid products having 79.0, MAIs 8.5, 9.5, 10.3, 13.8, 15.9, 21.6 and 22.8; 2,4-D Lithium Salt products having 85.0 and 95.0; 2,4-D Sodium Salt products having 17.5, and MAI 0.36; 2,4-D Alkanolamine Salt products having 59.7, 56.5, and 31.1; 2,4-D Butoxypropyl ester products having 67.2; 2,4-D Propylene Glycol Butyl Ether Ester products having 72.8, 41.0 and 68.6; and all other 2,4-D acid derivatives with aquatic uses.

12 The Agency has acceptable data on 2,4-D Butoxyethanol Ester. Data are required for 2,4-D Butoxypropyl Ester products with uses on corn, turf, forestry, pasture/rangeland, sorghum and ditchbanks; and 2,4-D Propylene Glycol Butyl Ether Ester products with uses on aquatic sites, corn, turf, pasture/rangeland and sorghum. Data are required for 2,4-D acid and all other salts, amines and esters with aquatic uses.

13 Data are required for 2,4-D Butoxyethanol Ester products with uses on corn, turf, forestry, rice, pasture/rangeland, sorghum, ditchbanks and aquatic uses; and 2,4-D Propylene Glycol Butyl Ether Ester products with uses on aquatic uses on aquatic sites, corn, turf, pasture/rangeland and sorghum. Data are also required for 2,4-D acid and all other salts, amines and esters with aquatic uses.

14 Data are required for 2,4-D Butoxyethanol Ester products with uses on corn, turf, forestry, rice, pasture/rangeland, sorghum, ditchbanks and aquatic uses. This data requirement is reserved for all other salts, amines and esters pending receipt and review of environmental fate data.

15 See Environmental Fate Data Table (§158.290, Guideline 165-5).

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.540 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	TEP	A,B,C,D,F,G	No		No[2]	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,C,D,G	No		No[3]	
122-1 - Vegetative Vigor	TGAI	A,B,C,D,G	No		No[3]	
122-2 - Aquatic Plant Growth	TGAI	A,B,C,D,G	No		No[3]	
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,C,D,G	No		Yes	9 Months
123-1 - Vegetative Vigor	TGAI	A,B,C,D,G	No		Yes	9 Months
123-2 - Aquatic Plant Growth	TGAI	A,B,C,D,G	No		Yes[4]	9 Months
TIER III						
124-1 - Terrestrial Field	TEP	A,B,C,D,G	No		Reserved[5]	
124-2 - Aquatic Field	TEP	A,B,C,D	No		Reserved[5]	

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

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§158.540 Plant Protection Footnotes

[1] Data must be submitted within the indicated timeframes, which begin on receipt of the Guidance Document.

[2] Not currently a requirement.

[3] Data are available in the open literature on the phytotoxicity of 2,4-D to broadleaf plants, therefore testing should be conducted at the Tier II level to establish EC_{50} values.

[4] Application to aquatic sites will require submission of data for five species of aquatic plants. Where the herbicide is applied to terrestrial sites, only the algae *Selenastrum capricornutum* is required.

[5] Reserved pending results of Tier II.

TABLE A
GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

§158.590 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact toxicity	TGAI	A,B,G	Yes	00036935	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,G	No		No[2]
141-4 - Honey bee subacute feeding study					Reserved[3]
141-5 - Field testing for pollinators	TEP	A,B,G	No		No[2]
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects					Reserved[4]
142-1 - Aquatic insect life-cycle study					Reserved[4]
142-3 - Simulated or actual field testing for aquatic insects					Reserved[4]

TABLE A

GENERIC DATA REQUIREMENTS FOR 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES					Reserved[4]	

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[1] Data must be submitted within the indicated timeframes, which begin on receipt of the Guidance Document.

[2] As data from the acute contact test indicate low toxicity, no further testing is required.

[3] Reserved pending development of test methodology.

[4] Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation[2]	Must Additional Data Be Submitted?	Timeframe for Submission[1]
Part 158 Subpart C- Product Chemistry					
Product Identity					
61-1 - Product Identity and Disclosure of Ingredients	MP	No	N/A	Yes[3]	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No	N/A	Yes[4]	6 Months
61-3 - Discussion of Formation of Impurities	MP	No	N/A	Yes[5]	6 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	MP	No	N/A	Yes[6]	12 Months
62-2 - Certification of Limits	MP	No	N/A	Yes[7]	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	No	N/A	Yes[8]	12 Months
Physical and Chemical Characteristics					
63-2 - Color	MP	No	N/A	Yes[9]	6 Months
63-3 - Physical State	MP	No	N/A	Yes9	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation[2]	Must Additional Data Be Submitted?	Timeframe for Submission[1]
Part 158 Subpart C - Product Chemistry (Continued)					
Physical and Chemical Characteristics (Continued)					
63-4 - Odor	MP		N/A	Yes[9]	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP		N/A	Yes[9]	6 Months
63-12 - pH	MP		N/A	Yes[9,10]	6 Months
63-14 - Oxidizing or Reducing Action	MP		N/A	Yes[9,11]	6 Months
63-15 - Flammability	MP		N/A	Yes[9,12]	6 Months
63-16 - Explodability	MP		N/A	Yes[9,13]	6 Months
63-17 - Storage Stability	MP		N/A	Yes[9]	15 Months
63-18 - Viscosity	MP		N/A	Yes[9,14]	6 Months
63-19 - Miscibility	MP		N/A	Yes[9,15]	6 Months
63-20 - Corrosion Characteristics	MP		N/A	Yes[9]	15 Months
Other Requirements					
64-1 - Submittal of samples	N/A		N/A	N/A	N/A

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Part 158
Subpart C - Product Chemistry

[1] Data must be submitted within the indicated timeframes, which begin on receipt of the Guidance Document.

[2] Not applicable. Although product chemistry data may been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

[3] The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common, and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

[4] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials. In order to assess the potential for contamination with halogenated dibenzo-p-dioxins and dibenzofurans, the description of the manufacturing process must also include the range of temperature conditions, pressure, and pH at each reaction step.

[5] A detailed discussion of all impurities that are or may be present at 0.1 percent or greater, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This discussion must also address the possible formation N-nitrosamines (amine formulations) and dibenzo-p-dioxins and dibenzofurans occurring in 2,4-D acid salts, and esters. Data submitted in response to the Data Call-In (DCI) Notices for analytical chemistry data on polyhalogenated dibenzo-p-dioxins/dibenzofurans in 2,4-D acid and its salts and esters may also partially fulfill this data requirement. These data are due as specified in the DCI Notice.

[6] Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used. All nitrosamines must be identified and quantified in six samples of each product containing the dimethylamine salt; two samples must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to at least 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for all nitrosamines, dibenzo-p-dioxins and dibenzofurans found. Certifications should be submitted on EPA Form 8570 Rev. 2-85.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Part 158
Subpart C - Product Chemistry

7 Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at $\geq$ 0.1 percent (w/w) and each "toxicologically significant" impurity present at < 0.1 percent (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present these include N-nitrosoamines (amine formulations), dibenzo-p-dioxins and dibenzofurans. Certifications must be submitted on EPA Form 8570 Rev. 2-85.

Data submitted in response to the Data Call-In (DCI) Notices for analytical chemistry data on polyhalogenated dibenzo-p-dioxins/dibenzofurans in 2,4-D acid and its salts and esters may also partially fulfill this data requirement. These data are due as specified in the DCI Notice.

8 Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

Data submitted in response to the Data Call-In (DCI) Notices for analytical chemistry data on polyhalogenated dibenzo-p-dioxins/dibenzofurans in 2,4-D acid and its salts and esters may also partially fulfill this data requirement. These data are due as specified in the DCI Notice.

9 Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

10 Data required if the test substance is dispersible in water.

11 Data required if the product contains oxidizing or reducing agents.

12 Data required if the product contains combustible liquids.

13 Data required if the product is potentially explosive.

14 Data required if the product is a liquid.

15 Data required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 2,4-DICHLOROPHENOXYACETIC ACID AND INORGANIC SALTS (2,4-D acid); AMINES AND ESTERS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.340 Toxicology					
ACUTE TESTING					
81-1 - Acute Oral Toxicity - Rat	MP	Yes	40448801	Yes[2]	9 Months
81-2 - Acute Dermal Toxicity	MP	Yes	40448802	Yes[2]	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	Yes	40448803	Yes[2]	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	40448804	Yes[2]	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	40448805	Yes[2]	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	Yes	40448806	Yes[2]	9 Months

[1] Data must be submitted within the indicated timeframes, which begin on receipt of the Guidance Document.

[2] The Agency has acceptable data on 2,4-D Diethanolamine Salt.

II. LABELING APPENDICES

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricul- tural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY - Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§156.10 Labeling Requirements for Pesticides and Devices.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ****" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978; amended at 53 FR 15952, May 4, 1988]

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

HEADING: All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

STORAGE INSTRUCTIONS: All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement:

   > "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   > "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

   > "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement:

> "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

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[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

    (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

    (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

    (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

    (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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MRID	Citation
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00004594	Rhodia, Incorporated (1971) Phenoxy Herbicides on Stubble Crop Rice. (Unpublished study received Nov 21, 1973 under 359-170; submitted by Rhone-Poulenc, Inc., Monmouth Junction, N.J.; CDL:230485-B)
00004610	Feeny, R.W.; Higham, J.W.; Snyder, E.H.; Colbert, D.R.; Agamalian, H. (1975) Avenge: (CL 84,777): Determination of CL 84,777(1,2-Dimethyl pyrazolium methyl sulfate) and Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) Residues in Barley Straw and Grain Following Ground Application (California): Report No. C-592. (Unpublished study received Jan 8, 1975 under 241-EX-64; prepared in cooperation with Lake Ontario Environmental Laboratory, submitted by American Cyanamid Co., Princeton, N.J.; CDL:224170-R)
00004666	Andreae, W.A.; Good, N.E. (1957) Studies on 3-Indoleacetic acid metabolism: IV. Conjugation with Aspartic acid and Ammonia as processes in the metabolism of Carboxylic acids. Plant Physiology 32(?):566-572. (Also in unpublished submission received Sep 16, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092090-F)
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00004677	Fites, R.C.; Slife, F.W.; Hanson, J.B. (1964) Translocation and metabolism of radioactive 2,4-D in jimsonweed. Weeds 12(?):180-183. (Also in unpublished submission received Sep 16, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092090-U)
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00004681	Holley, R.W.; Boyle, F.P.; Hand, D.B. (1950) Studies of the fate of radioactive 2,4-Dichlorophenoxyacetic acid in bean plants. Archives of Biochemistry and Biophysics 27(?):143-151. (Also unpublished submission received Sep 16, 1968 under 8F0676;submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092090-Y)
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00004689	Morgan, P.W.; Hall, W.C. (1963) Metabolism of 2,4-D by cotton and grain sorghum. Weeds 11(?):130-135. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092980-C)
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00004698	Weintraub, R.L.; Yeatman, J.N.; Lockhart, J.A.; Reinhart, J.H.;Fields, M. (1952) Metabolism of 2,4-Dichlorophenoxyacetic acid: II. Metabolism of the side chain by bean plants. Archives of Biochemistry and Biophysics 40(?):277-285. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092980-L)
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00004707	Gutenmann, W.H.; Hardee, D.D.; Holland, R.F.; Lisk, D.J. (1963) Residue studies with 2,4-Dichlorophenoxyacetic acid herbicide in the dairy cow and in a natural and artificial rumen. Journal of Dairy Science XLVI(11):1287-1288. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092980-V)
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00004723	Morton, H.L.; Robison, E.D.; Meyer, R.E. (1967) Persistence of 2,4-D, 2,4,5-T, and Dicamba in range forage grasses. Weeds 15 (?):268-271. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.;CDL:092980-AO)

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00004996	Corbett, J.R.; Miller, C.S. (1966) The persistence of 2,4-D in cotton when applied with desiccants. Weeds 14(?):34-37. (Also in unpublished submission received Sep 16, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.;CDL:092090-O)
00021755	Burnside, I. (1975) Crop Residue Report: FSDS No. A-8647. (Unpublished study received May 2, 1975 under 476-2156; prepared by Univ. of Nebraska, submitted by Stauffer Chemical Co., Richmond, Calif.;CDL:009609-K)
00022329	Grage, D.; Dietz, B.; Dietze, R.; et al. (1976) Sequential Applications of Eradicane 6.7-E (PPI) and 2,4-D (POES): Summary of Crop Residue Data on Corn. (Unpublished study received Apr 20, 1976 under 476-2157; prepared in cooperation with Morse Laboratories, Inc., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:224614-E)
00022622	Woofter, D.; Appleby, A.P.; Watson, V.H.; et al. (1972) [Chemical Sprays on Corn, Sorghum and Wheat]. Unpublished study received Jan 3, 1973 under 876-25; prepared in cooperation with Oregon State Univ. and others, submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:005052-C)
00025330	Suzuki, H.K.; Fenster, C.R. (1976) Dicamba: Residue Tolerance Petition--Proso Millet. (Unpublished study received Jan 24, 1979 under 9E2166; prepared in cooperation with Univ. of Nebraska,submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:097773-A)
00025338	Klausen-Rogers, G.; Renfrow, J.; Slater, L.; et al. (1970) Residue Results: [Dicamba]. (Unpublished study received Jun 15, 1973 under 1F1131; prepared in cooperation with Del Monte Corp. and others, submitted by Velsicol Chemical Corp., Chicago, Ill.;CDL:090907-F)

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00028173	Hoffman, C.; Haas, R.; Criswell, T.; et al. (1970) Grass: Project No. 404000. (Unpublished study received Jun 15, 1970 under 876-25; submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:004524-D)
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00033119	Washington State University (1963) [Residues of 2,4-D in Apples and Pears]. (Unpublished study received Dec 24, 1963 under 264-37; submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:001835-B)
00035913	Gangstad, E.O.; Zimmerman, P.W.; Hitchcock, A.E.; et al. (1974) Aquatic-Use Patterns for 2,4-D Dimethylamine and Integrated Control. By U.S. Dept. of the Army, Office of the Chief of Engineers, Aquatic Plant Control Program. Vicksburg, Miss.: U.S. Army Engineer, Waterways Experiment Station. (APCP technical report 7; published study; CDL:096474-C)
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00036169	Southwick, L.; Hartman, G.P.; Stritzke, J.; et al. (1975) A Residue Study of Picloram and 2,4-D in Oats and Barley following Postemergence Application of Tordon: 202 Herbicide: GHP-912. (Unpublished study received Jul 3, 1975 under 6F1653; prepared in cooperation with Univ. of Montana and others, submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:094498-D)

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MRID	Citation
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00043280	Whitney, E.W.; Montgomery, A.B.; Martin, E.C.; et al. (1968) The effects of a 2,4-D application on the biota and water quality in Currituck Sound, North Carolina. [Without title]? (?):13-17. (Also in unpublished submission received Aug 4, 1976 under 876-222; submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:242936-D)
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MRID	Citation
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00050678	McCann, J.A. (1970) Combination of Component A & B of Emulsamine E-3: Bluegill (Lepomis macrochirus): Test No. 243. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, unpublished study; CDL:130743-A)
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IV. FORMS APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE

SIGNATURE

DATE

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

OMB Approval No. 2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.______________________________ Date________________________________

Guidance Document for____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

OMB Approval No. 2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No.______________________________ Date__________________________________

Guidance Document for____

			I am complying with data requirements by		
Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization,				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

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GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:____________________
Registrant's Name and Address: ____
____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _________ concerning a requirement for submission of "generic" data on the active ingredient _______________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ___________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _________ and their registration number(s) is/are __________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative:______________________________(Signature)
Dated: ____________________ ______________________________(Typed)
EPA Form 8570-27